Farcoderm
TESTED WELLNESS

Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®): double blind, randomized clinical trial of efficacy and safety

INTERNATIONAL COMMERCIAL TELEVISION INC.

DermaWand®

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with certified UNI EN ISO 9001:2008 quality management system by Certiquality S.r.l.

KEY PERSONNEL

Customer

International Commercial Television Inc.
489 Devon Park Drive, Suite 315
19087 - Wayne, PA - United States of America (USA)

in site Study Director / Quality control

dr. **Vincenzo NOBILE**
International Development Coordinator
Biologist

Principal investigator

dr. **Enza CESTONE**
Degree in Medicine and Surgery, Specialist in Dermatology and Venereology
Consultant to Farcoderm s.r.l.

Farcoderm srl

Farcoderm srl	Via Angelini, 21 27028 San Martino Siccomario (PV) Technical director: dr. **Angela MICHELOTTI** (Biologist)

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

1. TITLE PAGE

"Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®): double blind, randomized clinical trial of efficacy and safety"

1.1. Test product:	DermaWand®
1.2. Indication studied:	Improvement of skin condition
1.3. Sponsor:	INTERNATIONAL COMMERCIAL TELEVISION INC.
1.4. Protocol number:	FU.04.C.L_2013/GCP01 final version no. 3 by 20.01.2014
1.5. Development phase of the study:	Post-market
1.6. Study period:	
1.6.1. date of first enrolment:	31.01.2014
1.6.2. date of last completed:	09.11.2014
1.7. Date of early study termination:	None
1.8. Principal investigator:	
1.8.1. Name:	Dr Enza Cestone, MD, Specialist in Dermatology and Venereology
1.8.2. Affiliation:	Consultant to Farcoderm srl
1.9. Person responsible for study report:	
1.9.1. Name:	Dr Vincenzo Nobile, Biologist, Farcoderm srl
1.9.2. Address:	Via Mons. Angelini, 21
	27028 San Martino Siccomario (PV)
1.9.3. Telephone number:	+39 (0)382 25504
1.9.4. Fax number:	+39 (0)382 536006
1.9.5. e-mail address:	vincenzo.nobile@farcoderm.com
1.10. Date of the report:	10.12.2014

This study was carried out in compliance with Good Clinical Practices (ICH guideline for good clinical practice E6(R1) version 4).

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

2. SYNOPSIS

The table here below reports a brief synopsis summarizing the study.

2.1. Name of Sponsor/Company INTERNATIONAL COMMERCIAL TELEVISION INC.	**SYNOPSIS**
2.2. Name of test product: DermaWand®	
2.3. Title of the study Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®): double blind, randomized clinical trial of efficacy and safety	
2.4. Investigator(s): Dr Enza Cestone, MD, Specialist in Dermatology and Venereology	
2.5. Study centre(s): Farcoderm srl - Via Mons. Angelini, 21 - 27028 San Martino Siccomario (PV)	
2.6. Studied period: 2.6.1. First enrolment: 31.01.2014 2.6.2. Last completed: 09.11.2014	2.7. Phase of development: Post-market
2.7. Objectives: The primary objective of the study was to assess the safety of use and the efficacy of DermaWand® in decreasing the clinical signs of skin ageing (wrinkles and skin sagging). The secondary objective of the study was to assess the efficacy of DermaWand® on skin parameter related to the skin ageing process (skin moisturization, skin elasticity, skin radiance, eyebags, and skin pores size).	
2.8. Methodology Non-invasive bioengineering techniques Clinical analysis Self-assessment	
2.9. Number of subjects: 2.9.1. Planned: 2.9.2. Analysed:	 110 84
2.10 Main Criteria for inclusion Age between 30 to 70 years old, skin wrinkledness all over the face (crow's feet area/nasolabial fold/wrinkles under the eyes), and bags under the eyes.	
2.11. Test product, way of use, batch number: 2.11.1. Test product: 2.11.2. Way of use: 2.11.3. Batch number:	 DermaWand® Reported in attachment Not available
2.12. Duration of treatment: 30 days	
2.13. Placebo product, way of use, batch number: 2.11.1. Test product: 2.11.2. Way of use: 2.11.3. Batch number:	 DermaWand® placebo Reported in attachment Not available
2.14. Criteria for evaluation: 2.14.1. Safety: 2.14.2. Efficacy:	 Analysis of the adverse events Statistical analysis of parameter variation
2.15. Statistical methods: Two-way test t of Student for paired and unpaired data for instrumental data. Mann-Whitney test for clinical data.	

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

2.1. Name of Sponsor/Company International Commercial Television Inc. 2.2. Name of test product: DermaWand®	**SYNOPSIS**
2.3. Title of the study Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®): double blind, randomized clinical trial of efficacy and safety	
2.16. Summary conclusions:	
2.16.1. Efficacy results:	Dermawand® use determines the following variations of the parameters measured in the study: Crow's feet wrinkle depth: -10.1% Nasolabial fold depth: -5.5% Underneath eye wrinkle depth: -6.5% Pores Surface: -9.6% Eyebags volume: +0.4% Skin moisturization: +18.1% Skin radiance: +27.8% Skin elasticity: +9.5% Clinical analysis Wrinkledness on neck: 27.9%* Wrinkledness on face: 48.8%* Appearance of eyebags: 20.9%* Global appearance of the skin: 76.7%* * % of subjects who had an improvement.
2.16.2. Safety results:	CEs: 0% AEs: 4.7% (n = 2 subjects) SAEs: 0%
2.16.3. Conclusion:	Dermawand® use determined a decrease of the hairline to eyebrows line distance as measured according the technique reported elsewhere in this report. A decrease of the hairline to eyebrows line distance indicates a decrease of the sagging of the eyebrows skin. Based on the results obtained is possible then to conclude that Dermawand® has a lifting effect for the eyebrows skin. During the study period the product was well tolerated, since neither cosmetic nor adverse events were reported by the subjects participating in the study.
2.16.4. Date of the report:	10.12.2014

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

3. TABLE OF CONTENTS FOR THE INDIVIDUAL CLINICAL STUDY REPORT

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

4. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	Adverse event
CCCS	Clinical Compliance Control System
CRF	Case Report Form
ICF	Informed consent form
ITT	Intention To Treat
PP	Per Protocol
SAE	Severe adverse event
SEM	Standard error of the Mean
SOP	Standard Operative Procedure

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

5. ETHICS

5.1. Independent Ethics Committee (IEC)

The protocol and its amendment were approved by the "Independent Ethical Committee for Non-Pharmacological Clinical trials" (attachment 15.1.1) during its meeting on 17.12.2013 and on 06.02.2014. The study protocol was amended on 20.01.2014 before study protocol submission to the ethical committee. The table here below reports the study protocol revision history.

Table 5.1.1. Study protocol tracking.

Version	Date	Description	Author
1.0	27.11.2013	First draft	Enza Cestone, Vincenzo Nobile
2.0	02.12.2013	Panel size was enlarged from 100 to 110 in order to finish the study on 50 + 50 volunteers (drop-out rate 10%) - § 7.1.3. Variation of the treatment time from 5 minutes to 8-10 minutes. - § 7.1.3. Added the use of a pre-treatment cream	Kelvin Claney, Vincenzo Nobile
3.0	20.01.2014	Added the assessment of neck wrinkles under § 8.6 page 12 - Removed "Tattoo or permanent make-up" exclusion criteria	Kelly Willet, Vincenzo Nobile, Enza Cestone

5.2. Ethical conduct of the study

The study was conducted in accordance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amendments) and the guideline for Good Clinical Practice E6(R1) (ICH harmonised tripartite guideline current step 4 version dated 10 June 1996).

5.3. Patient information and consent

Before to participate in the study, subjects were informed by the investigator about the product to be tested, the study risk and benefit, and the study procedures. Informed consent form (ICF) was then obtained before the subject entered the study. Original signed copies of each ICF were retained in the study file. During the study there was no need to revise the ICF and all the subjects were supplied with the final version (version no. 3.0 dated 28.01.2014, attachment 15.1.2) of the ICF. The table here below reports the ICF revision history.

Table 5.3.1. ICF tracking.

Version	Date	Description	Used
1.0	28.11.2013	First draft	No
2.0	02.12.2013	Minor revision (category of the product to be tested)	No
3.0	28.01.2014	Minor revision (Investigator name)	Yes

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

The study took place at Farcoderm s.r.l. dermatological facilities in San Martino Siccomario (PV), Italy. Farcoderm s.r.l. is an independent testing laboratory, for *in vitro* and *in vivo* safety and efficacy assessment of cosmetics, food supplements and medical devices. The table 6.1 reports the list of the persons involved in the study. The Curriculum vitae of the Principal investigator and the Study Director is reported in the attachment 15.2.

7. INTRODUCTION

The DermaWand® is a condensed version of the high frequency skin care technology that is used by skincare professionals worldwide to enhance the appearance of the skin. DermaWand® works by stimulating the skin using a version of "micro-current" technology that was originally invented over 100 years ago by the famous scientist Nikola Tesla. The device sends gentle micro-current impulses to the dermis at a rate close to 100,000 cycles per second thus placing this micro-current in the radio frequency spectrum. This action gently massages the skin and increases the circulation, while at the same time the passage of the micro-current through the dermis causes a heating effect, which is suspected of aiding and improving natural production of collagen and elastin. Further, it is thought that the passage of the micro-current aggravates the muscles causing them to uptake water from the surrounding tissue for protection. This intake of fluid causes the tissues to swell through this intake and the end result is a reduction or "blowing out" of fine lines and wrinkles.

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

The study carried out was aimed to assess the safety of use and the efficacy of DermaWand® (post-market study). In order to reach this goal 110 female subjects showing the clinical signs of skin wrinkledness all over the face (crow's feet area/nasolabial fold/wrinkles under the eyes), and bags under the eyes were enrolled. Product safety of use and efficacy were assessed before and after 30 days of product use. Measurements were performed using non-invasive bioengineering, clinical analysis and self-assessment techniques currently used in the dermatological field. The study protocol was drafted according to the Good Clinical Practice E6(R1), and the current protocols used in the dermatological field to assess skin properties.

Table 6.1. Delegation log.

Print name	Study role	Initials	*Tasks delegated
Enza Cestone	Principal investigator	CE	1, 2, 3, 4, 5, 6, 7, 8, 12, 13, 15, 16
Marta Pisati	Co-investigator	MP	6, 7, 11, 12, 13, 16
Gloria Roveda	Co-investigator	GR	1, 2, 3, 4, 5, 6, 7, 8, 12, 13, 15, 16
Cristina Scillironi	Assistant	CS	11, 13, 16
Tatiana Gullo	Secretary	TG	14
Sabrina Camera	Secretary	SC	14, 18
Vincenzo Nobile	Director	VN	9, 10, 16, 17

*Tasks delegated			
1. Obtain Informed Consent	6. Perform measurements	11. Digital photography	16. Recording/Reporting
2. Obtain medical history	7. Completion of CRFs	12. Set up and maintenance of ISF	deviations/Violations
3. Perform physical examination	8. CRF signature	13. Product dispensino	17. Study Reporting and Statistics
4. Inclusion/exclusion assessment	9. Data query completion	14. Product accountability	18. Products labelling
5. Medical care of patients	10. Data query signature	15. Assessment of SAEs	

8. STUDY OBJECTIVES

The primary objective of the study was to assess the safety of use and the efficacy of DermaWand® in decreasing the clinical signs of skin ageing (wrinkles and skin sagging). The secondary objective of the study was to assess the efficacy of DermaWand® on skin parameter related to the skin ageing process (skin moisturization, skin elasticity, skin radiance, eyebags, and skin pores size).

9. INVESTIGATIONAL PLAN

9.1. OVERALL STUDY DESIGN AND PLAN - DESCRIPTION

This was a monocentric, parallel groups, placebo-controlled, inter- and intra-group comparison study. The study was carried out at Farcoderm s.r.l. (27028 San Martino Siccomario, PV, Italy) dermatological facilities. It was planned to enroll 110 adult female subjects showing skin wrinkledness all over the face in order to have 100 subjects finishing the study (assuming an anticipate drop-out rate by 10%). The study was controlled using a placebo device. Subjects were assigned to active or placebo group using a computer generated randomization list (attachment 15.3) based on their number of entrance in the study. The study duration for each subject was 30 days. Measurement were carried out before and after 30 days of product use. The study was carried out according the protocol shared with the Sponsor of the study. Data were collected in the CRF (sample reported in attachment 15.1.3). The study flow-chart is reported in figure 1 and the schedule of assessments is reported in table 9.1.1.

9.2. DISCUSSION OF STUDY DESIGN, INCLUDING THE CHOICE OF CONTROL GROUP

A placebo-controlled, parallel groups clinical study was carried out in order to take into account: a) the physiological variation of skin properties all over the study period, and b) the effect of the massage due to the way of product use. The study was carried out under double blind conditions in order to minimize biases. Only subjects having and adequate rest period were enrolled in order to avoid carry over effects. The placebo product is the DermaWand® device without the electronic needed to produce high frequency, low level micro-current pulsations.

9.3. SELECTION OF STUDY POPULATION

110 female subjects were randomized. Withdrawn/lost to follow-up/drop-out subjects were not replaced. All inclusion and non-inclusion criteria were checked by the principal investigator or delegate, through a questionnaire during the screening visit. Subjects were assigned a screening number in the chronological order of their inclusion in the study at screening visit, and a randomization number after the completion of the randomization visit.

Figure 1. Study flow chart

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

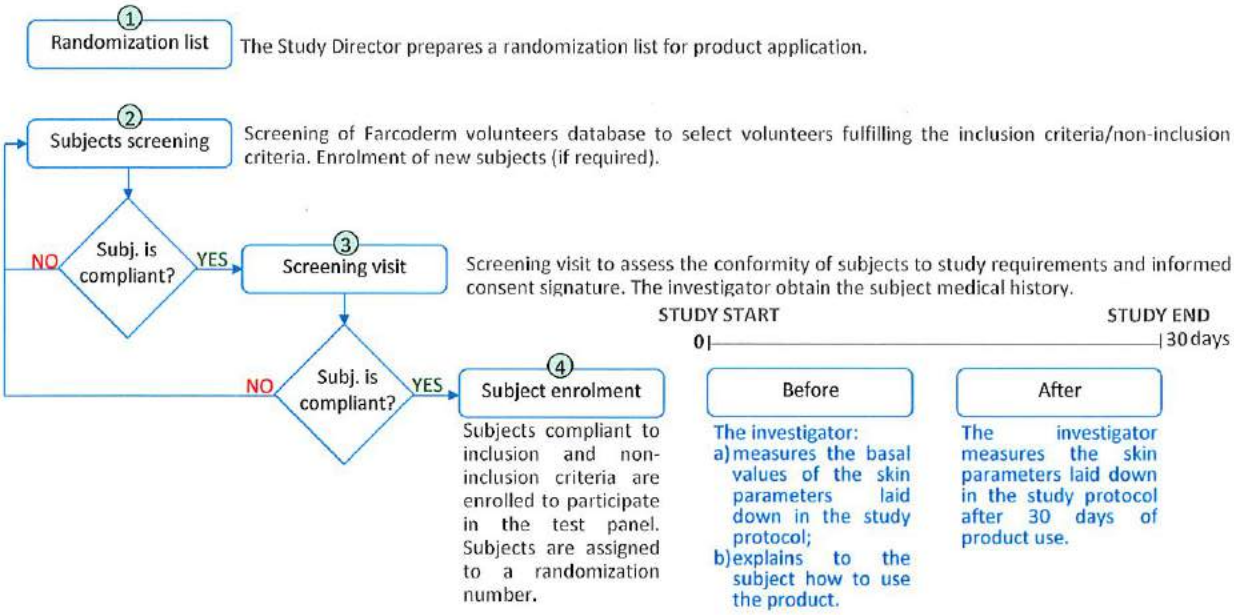


Table 9.1.1. Schedule of assessments.

Assessment	0	1 month
Informed consent	X	
History	X	
Effectiveness:		
Skin moisturization	X	X
Skin elasticity	X	X
Wrinkle depth	X	X
Bags under the eyes volume	X	X
Pore size	X	X
Skin radiance	X	X
Clinical analysis	X	X
Self-assessment questionnaire		X
Safety:		
Adverse event		X
Serious adverse event		X

These numbers and code that identify each subject were documented in the case report form. Subjects were randomized in a 1:1 (active:placebo) ratio. The principal investigator maintained a record of all subjects who were considered screen-failed (i.e. subjects who signed the informed consent form and were not enrolled). For each subject, the primary reason for not enrollment were recorded. The principal investigator maintained also a record of all subjects enrolled and randomized.

9.3.1. Inclusion criteria

- ✓ Good general health
- ✓ Female sex
- ✓ Caucasian skin type
- ✓ Age between 30 to 70 years old
- ✓ Skin wrinkledness all over the face (crow's feet area/nasolabial fold/wrinkles under the eyes)
- ✓ Bags under the eyes
- ✓ Willingness to submit to before and after pictures using Primos 3-D Scanner/Camera
- ✓ Willingness to follow treatment procedures, twice a day, every day, for full 30 days
- ✓ Adequate rest period between two similar study

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

- ✓ Willingness to not use antiaging products during the study period
- ✓ Willingness to not vary the normal daily routine
- ✓ Subject is under effective contraception (oral/not oral) therapy

9.3.2. Non-Inclusion criteria

- Subject do not meet the inclusion criteria above
- Positive history for atopy or hypersensitive skin
- Past history of allergy or sensitivity to cosmetics, toiletries, to solar and / or topical medications
- Any skin condition that the principal investigator deems inappropriate for participation
- Pacemaker or internal defibrillator, or other implanted metallic or electronic device
- Permanent implant in the treated area such as metal plates and screws or silicon, unless deep enough in the periosteal plane
- Intra-dermal or superficial sub-dermal areas have been injected with Botox/HA/collagen/fat injections or other augmentation methods with bio-material during the last six months
- Current or history of skin cancer, or any other type of cancer, or pre-malignant moles
- Severe concurrent conditions, such as cardiac disorders
- Pregnancy or nursing
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, such as sores, psoriasis, eczema, and rash
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin
- History of bleeding coagulopathies, or use of anticoagulants in the last ten days
- Any facial surgery performed within 12 months prior to treatment
- Facial dermabrasion, facial resurfacing, or deep chemical peeling with the last 3 months
- Treatment with light, laser, radio or ultra frequency, or other devices in the past 6 months
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment
- Drug addict, alcoholic
- Pregnant or breastfeeding women
- Adult protected by the law (under guardianship, or hospitalized in a public or private institution, for a reason other than the research, or incarcerated).

Volunteer is unable to communicate or cooperate with the Investigator due to language problems, poor mental development, or impaired cerebral function.

9.3.3. Removal of subjects from treatment or assessment

A subject accepted into the study may be withdrawn or considered to have "dropped out" by the investigator if:

- a side effect attributable to the treatment is judged severe,
- the subject develops a systemic illness (unrelated to the study treatment but occurring during the study),
- a concomitant medication, likely to interfere with the results of the study, is taken by the subject,
- the protocol requirements have not been respected.

The subjects are entitled to discontinue the study for any reason at any time if they desire. Should this occur, the investigator or designee determines the reasons in order to know if it is linked to the study or not and the primary reason are recorded in the case report form (CRF). If the subject has withdrawn due to Serious Adverse Event (SAE) the subject are followed until Serious Adverse Event (SAE) resolution. In the case where the subject does not present for a visit, the investigator or designee attempts to contact the subject by telephone on two consecutive occasions. The subject are considered as lost to follow-up if the investigator or designee fails to reach her. These attempts and the result are recorded on source document.

9.4. TREATMENTS

9.4.1. Treatments administered

Subjects received DermaWand® active or placebo according to their number of entrance in the study. DermaWand® (Figure 2) is a small, electric, hand-held device that creates ultra or high frequency, low level

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

micro-current pulsations that massage the skin at up to 100,000 cycles per second. The placebo device is the same as DermaWand® active but without the electronic needed to produce high frequency, low level micro-current pulsations. No visible differences existed between the DermaWand® and the placebo device. Both the DermaWand® and the placebo device were used, at home, according the way of use reported in attachment 15.4. During devices use subjects used also 2 cosmetic products (attachment 15.5).

Figure 2. DermaWand®

9.4.2. Identity of investigational product(s)

The DermaWand® and the placebo devices were labeled by the *in site* study director, according to the randomization list, as showed in the figure here below.

Figure 3. Product label.

Study no. FU.04.C.L_2014/0297
SUBJECT XXX*

* from 001 to 110

9.4.3. Method of assigning subjects to treatment groups

Subjects were assigned to treatment groups using a computer-generated, using PASS 11 statistical software (version 11.0.8 for Windows; PASS, LLC. Kaysville, UT, USA) restricted randomization list (biased coin using Efron's algorithm). The software was running on Windows Server 2008 R2 Standard SP1.

9.4.4. Selection of doses in the study

Not applicable.

9.4.5. Selection and timing of doses for each subject

Not applicable.

9.4.6. Blinding

Subjects, investigator and her collaborators were kept blind to products assignment. Both the DermaWand® active and the placebo devices were similar in shape and no visible differences existed between them. Sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation, where prepared for each subject and stored in a safe place by the *in site* study Director.

9.4.7. Prior and concomitant therapy

Not applicable.

9.4.8. Treatment compliance

The compliance to treatment was assessed using the triacys system. A device called CCCS (Clinical Compliance Control System) was given to each subject in order to walk them through the protocol and record their gestures. CCCS recorded (1 image per second) subjects during product(s) use. The data recorded by CCCS were transferred

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

into a database and qualified operators analyzed the images in order to search for subjects compliance.

9.5. EFFICACY AND SAFETY VARIABLES

9.5.1. Efficacy and Safety measurements assessed

Efficacy and safety measurements were assessed before (basal value) and 30 days after product(s) use. Measurements were carried out (on cleansed skin) by the principal investigator or the co-investigators. Each subject was measured by the same person at each visit in order to minimize intrinsic subject-to-subject variations. The efficacy and safety measurements are detailed in the sections here below.

9.5.1.1. EFFICACY VARIABLES

The sections here below report the efficacy and safety variables measured during the study. The schedule of assessments is reported in table 9.1.1.

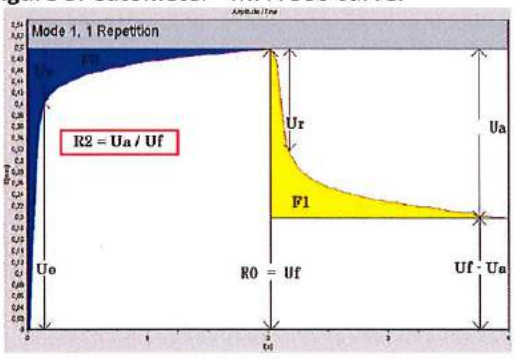
9.5.1.1.1. Skin moisturization

The measurement of the skin moisturization was based on the internationally recognized Corneometer® method. Corneometer® method is based on the dielectric constant of water. The probe shows changes of capacitance according to the moisture content of the measuring object. An electric scatter field penetrates the very first layers of the skin and determines the dielectricity. The used device is the Corneometer CM 825 (Courage+Khazaka, electronic GmbH). Skin moisturization was measured in the right cheek in 5 points.

9.5.1.1.2. Skin elasticity

The measurement of skin elasticity was based on the suction method using a negative pressure deforming the skin mechanically (Cutometer® method). A Negative pressure was created in the device and the skin was drawn into the aperture of the probe for 3 seconds and after a defined time released again. Inside the probe, the penetration depth was determined by a non-contact optical measuring system. This optical measuring system consists of a light source and a light receptor, as well as two prisms facing each other, which project the light from transmitter to receptor. The light intensity varies due to the penetration depth of the skin. The resistance of the skin to the negative pressure (firmness) and its ability to return into its original position (elasticity) are displayed as curves (penetration depth in mm/time) in real time during the measurement. The used device is the Cutometer® MPA 580 (Courage+Khazaka, electronic GmbH). Skin elasticity was measured in the middle of the right cheek. Elasticity was measured as the ratio between the maximum elongation (Uf) and the residual deformation (Ua) of the skin. This parameter is known as R2 and indicates the ability of the skin to return to its basal state after deformation. For further information see figure 3.

Figure 3. Cutometer® MPA 580 curve.



Instrument setup.

Pressure	450 mbar
On-time:	2 seconds
Off-time:	2 seconds
Cycles:	3
Meas. time:	12 seconds

9.5.1.1.3. Skin profilometry (wrinkles depth, bags under the eyes volume and pore size)

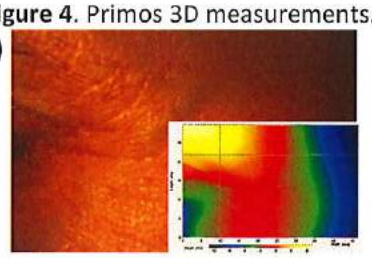
Skin surface properties were quantitatively assessed by Primos 3D (GFM Messtechnik GmbH). Primos 3D is a non-contact *in vivo* skin measurement device based on structured light projection (figure 4a). In conjunction with a comprehensive 3D measurement and an

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

evaluation software, the sensor allows to measure skin surface properties (i.e. wrinkle depth, volume, roughness etc.). In this study were calculated the wrinkle depth (figure 4b), the eyebags volume (4c), and the pores size (figure 4d).

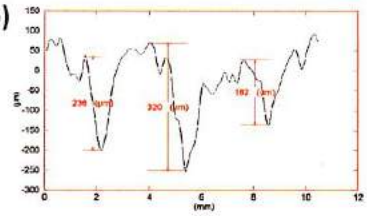
Figure 4. Primos 3D measurements.

a)



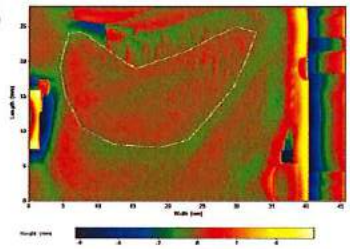
The technique. Primos 3D is a 3D scanner that create a point cloud (set of vertices in a three-dimensional coordinate system) of geometric samples on the surface of the subject. These points are then used to extrapolate the shape of the subject (a process called reconstruction). Like cameras, 3D-scanner have a cone-like field of view, and like cameras, they can only collect information about surfaces that are not obscured. While a camera collects color information about surfaces within its field of view, 3D scanners collect distance information about surfaces within its field of view. The "picture" produced by a 3D scanner describes the distance to a surface at each point in the picture (see the image in the insert).

b)



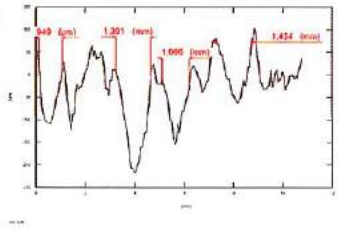
Wrinkle depth measurement. Wrinkle depth is measured as the height of wrinkles in the region of interest: This calculation is done on the sectional picture (wrinkle depth vs. section). The wrinkle volume is calculated below a reference plane on the sectional picture along all the wrinkle length.

c)



Bags under the eyes measurement. The volume of the bags under the eyes is measured in the region of interest (ROI, bag under the eye). The software allows to calculate the volume of the bag under the eyes as the rising from a reference plane (skin area not affected by the bag).

d)



Pore size measurement. Pore size is measured as the transverse section (diameter) of the pore size in the region of interest.

9.5.1.1.4. Digital macrophotography

Skin radiance was measured using a CM-700D spectrophotometer/colorimeter (Konica Minolta). The radiance is assessed by means of the gloss parameter measurement. The gloss parameter measures the specular component of the reflected light and correlates with the skin radiance (ability of the skin to reflect the light).

9.5.1.1.5. Digital macrophotography

Photographic pictures were taken, under standard lighting conditions, using a professional digital reflex camera NIKON D300 digital camera, Nikon Corporation Tokyo, Japan) equipped with a macro-objective (AF-S Micro NIKKOR 60mm f/2.8G ED, Nikon Corporation Tokyo, Japan), an independent flash system (Kit R1C1, Nikon Corporation Tokyo, Japan) and cross- and parallel-polarized filters.

9.5.1.1.6. Clinical analysis

The dermatologist using a clinical score scale (table 9.5.1.1.6.1.) assessed: a) the skin wrinkledness (face and neck skin wrinkles evaluation), b) the appearance of the bags under the

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

eyes, c) the appearance of the skin (global evaluation).

Table 9.5.1.1.6.1. Clinical scoring.

	Score
No visible effect	1
Mild visible effect	2
Moderate visible effect	3
Evident visible effect	4

9.5.1.1.7. Self-assessment questionnaire

Subjects were asked to reply to the questions of a self-assessment questionnaire (table 9.5.1.1.7.1).

Table 9.5.1.1.7.1. Self-assessment questionnaire.

No.	Item	Answers	
01	Was DermaWand easy to use?	☐ Yes	☐ No
02	Does your face look/feel younger?	☐ Yes	☐ No
03	Do you feel the appearance of your skin has improved?	☐ Yes	☐ No
04	Does your face feel tighter?	☐ Yes	☐ No
05	Do your wrinkles appear less prominent?	☐ Yes	☐ No
06	Does your face look more radiant?	☐ Yes	☐ No
07	Does your skin feel moister?	☐ Yes	☐ No
08	Do you feel the bags under your eyes are less noticeable?	☐ Yes	☐ No
09	Do you feel your skin's complexion looks more even?	☐ Yes	☐ No
10	Does your skin feel rejuvenated?	☐ Yes	☐ No
11	Does your skin look healthier?	☐ Yes	☐ No
12	Does your skin look smoother?	☐ Yes	☐ No
13	Does your skin feel less dry?	☐ Yes	☐ No
14	Do your eyelid and eyebrows look more lifted?	☐ Yes	☐ No
15	Does the area around your eyebrow look tighter?	☐ Yes	☐ No
16	Do you feel your wrinkles are less noticeable?	☐ Yes	☐ No
17	Do you feel your crow's feet are less noticeable?	☐ Yes	☐ No
18	Do you feel there has been a reduction in puffiness?	☐ Yes	☐ No
19	Does your face feel more refreshed and stimulated?	☐ Yes	☐ No
20	Do you feel your skin tone has improved?	☐ Yes	☐ No
21	Do you feel there has been an increase in circulation?	☐ Yes	☐ No
22	Do you feel that the "folds" of your skin have been reduced?	☐ Yes	☐ No
23	Do you feel like the lines on your forehead have been reduced?	☐ Yes	☐ No
24	Do you feel you look 10 years younger?	☐ Yes	☐ No
25	Does your skin appear more-even toned?	☐ Yes	☐ No
26	Does the skin on your neck appear tighter?	☐ Yes	☐ No
27	Do you notice any improvement in your facial complexion?	☐ Yes	☐ No
28	Does your skin feel more alive?	☐ Yes	☐ No
29	Would you recommend DermaWand to your friends?	☐ Yes	☐ No

9.5.1.2. SAFETY VARIABLES

The tolerability of the treatment was closely followed by the principal investigator during the course of the study. Subjects had access to the investigator in case of intolerance reactions via a contact phone number provided with the informed consent form. If a subject reports an event, the principal investigator has to decide if it is pertinent or not. If yes, she reports it as a cosmetic or an adverse event. Any unexpected related side effect judged as severe by the principal investigator are reported to the Sponsor. Upon investigator judgment, the subject may be withdrawn from the study and the side effect are followed until resolution (maximum until the end of the study).

9.5.1.2.1. Adverse Event (AE)

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

An adverse event (AE) is any untoward medical occurrence in a subject or any untoward and unintended response to the product to be tested whether or not related to the device and/or the cosmetic product(s). Pre-existing conditions that worsen during a study are to be reported as AE. This definition includes events occurring from the time of the subject giving informed consent until the end of the study including the follow-up period. Each symptom has to be reported separately on AE form.

Intensity Classification. AEs are classified as mild, moderate or severe according to the following criteria:

Mild:	symptoms do not alter the subject's normal functioning
Moderate:	symptoms produce some degree of impairment to function, but are not hazardous, uncomfortable or embarrassing to the subject
Severe:	symptoms definitely hazardous to well-being, significant impairment of function or incapacitation.

Causality Classification. The relationship of an AE to the treatment is classified according to the following:

Related:	reports including good reasons and sufficient information to assume a causal relationship with the medical device and/or cosmetic product and/or study protocol .
Not related:	reports including good reasons and sufficient information to rule out a causal relationship with the medical device and other cosmetic products delivered.

If causality is not provided or not possible to classify as "Related" nor as "Not related" it will be classified as "Related".

Any adverse event judged by the principal investigator as related to product to be tested will be reported by the investigator to the sponsor within 48 hours following its confirmation by the investigator on a case by case basis depending on the nature of the adverse event.

All observed AEs whether or not related to the product, will be recorded on the cosmetic/adverse event page(s) of the CRF at each scheduled visit. Adverse Events involving treatment reactions, accidents, illnesses with onset during the treatment phase of the study, or exacerbation's of pre-existing illnesses should be recorded. For all AEs, the principal investigator will have to assess the duration, the severity and the causality of the events on a case-by-case basis to ensure safety of the subject(s) taking part in the study. The investigator may stop the study if the study reveals a risk to the health of the subject, on condition that the sponsor is notified within 24 hours of the action(s) taken. For all AEs, subjects will need to be followed until the resolution of the AE (maximum, end of the study). All new information will have to be reported into the source document and into the AE CRF page.

9.5.1.2.2. Serious Adverse Events (SAEs)

A serious adverse event must be communicated immediately (within 24h of the investigator's knowledge of the event) by the investigator to the sponsor. Any additional information requested by the Sponsor must be provided within a period of 5 days following receipt of the form. The Sponsor will ensure that the reporting is performed in accordance with applicable regulatory requirements.

When a subject is withdrawn due to a SAE the investigator will provide or arrange for appropriate follow-up and will document the course of the subject's condition. The investigator should follow the procedures to assess the safety of the treatment

Definition of a SAE: any AE occurring at any time that:

- led to death;
- led to a serious deterioration in the health of the subject that:
- resulted in a life-threatening illness or injury

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

- resulted in a permanent impairment of a body function or permanent damage to a body structure;
- required in-patient hospitalization or prolongation of existing hospitalization
- resulted in medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure
- led to a fetal distress, fetal death or a congenital abnormality or birth defect

For all SAEs, subjects will need to be followed until resolution of the AE. In this study is not expected the occurrence of SAEs.

9.5.2. Appropriateness of measurements

The safety and efficacy measurements are widely used in the dermatological field. The efficacy measurements are carried out according SOPs implemented at the testing facility.

9.5.3. Primary efficacy variable(s)

The primary efficacy variable is the wrinkle depth measurement.

9.6. DATA QUALITY ASSURANCE

All the study documents and procedures were subject to quality assurance procedures. All the measurements were carried out according to specific SOPs implemented in the testing facilities. All the study staff had access to SOPs and was adequately trained on them. A site initiation visit was performed by Sponsor staff (attachment 15.6).

9.7. STATISTICAL METHODS PLANNED IN THE PROTOCOL AND DETERMINATION OF SAMPLE SIZE

9.7.1. Statistical analysis and analytical plan

Efficacy analysis is based on the Per Protocol Population. The per-protocol (PP) population is defined as all subjects who completed the study without any major protocol violations. Analysis of safety was based on the Intention to treat population that is defined as all subjects that have been assigned a subject number and received at least one study treatment. The statistical criteria applied is as follows: a) for intragroup (after vs. before) comparisons a two-way t test of Student for paired data was carried out, and b) for intergroup (active vs. placebo) comparisons a two-way t test of Student for unpaired data was carried out. Mann-Whitney test was used for clinical and self-assessment questionnaire comparisons. Statistical analysis was carried out using: a Microsoft® Excel® 2013 (15.0.4649.1000) 32 bit version worksheet running on Microsoft® Windows 8.1 Professional 64 bit version, and NCCS statistical software (version 8.0.20 for Windows; NCCS, LLC. Kaysville, UT, USA) running on Windows Server 2008 R2 Standard SP1..

9.7.2. Determination of sample size

Based on laboratory experience a sample size by 20 is enough to demonstrate the produce efficacy.

9.8. CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSIS

No changes were recorded in the conduct of the study or in the planned analysis.

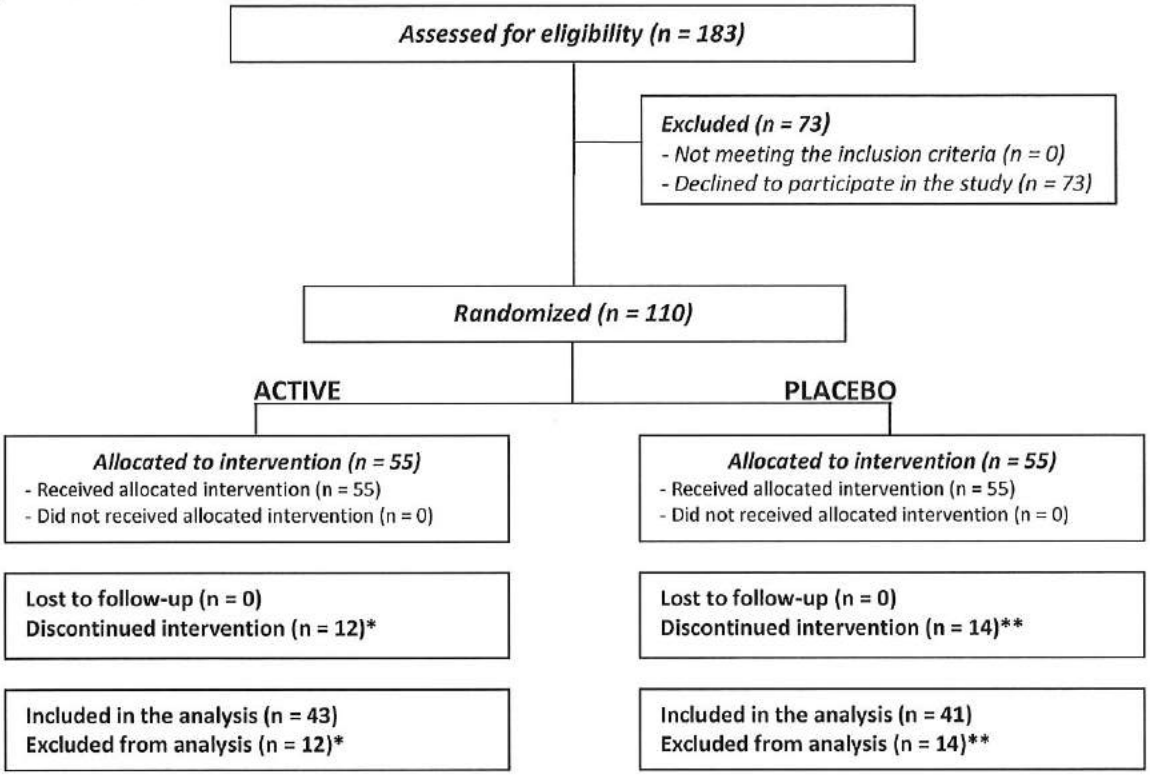
Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

10. STUDY SUBJECTS

10.1. DISPOSITION OF SUBJECTS

A total of 110 subjects were randomized in the study. The disposition of the subjects is reported in figure 5.

Figure 5. Flow chart



** 2 subjects experienced headache (drop out). It was not possible to assess the correlation between product use and the adverse event. 10 subjects referred to be not interested to continue in product use since it is challenging in relation to the way of use and the frequency of use.*

*** 14 subjects referred to be not interested to continue in product use since it is challenging in relation to the way of use and the frequency of use.*

10.2. PROTOCOL DEVIATIONS

No protocol deviations were recorded in the study period.

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

11. EFFICACY EVALUATION

11.1. DATA SETS ANALYZED

The data set analyzed was formed by 43 subjects in the active group and 41 subjects in the placebo group.

11.2. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

The demographic and baseline characteristics are reported in table 11.2.1.

Table 11.2.1. Demographic and baseline characteristics.

	Active treatment	Placebo treatment
Sample size	43	41
Wrinkle depth:		
Crow's feet (µm)	309.5 ± 9.5	302.9 ± 12.6
Nasolabial fold (µm)	521.2 ± 22.3	527.6 ± 21.1
Underneath eye (µm)	241.2 ± 10.0	242.5 ± 11.1
Pores size	0.5657 ± 0.0177	0.5702 ± 0.0191
Eyebags volume (mm^3)	19.3600 ± 0.7560	20.0587 ± 0.8252
Skin moisturization (c.u.)	39.7 ± 1.3	38.9 ± 1.2
Skin elasticity (Ua/Uf)	0.6597 ± 0.0082	0.6696 ± 0.0092
Skin radiance (a.u.)	7.67 ± 0.34	8.09 ± 0.37

11.3. EFFICACY RESULTS AND TABULATIONS OF INDIVIDUAL PATIENTS

11.3.1. Analysis of efficacy

11.3.1.1. Wrinkles depth

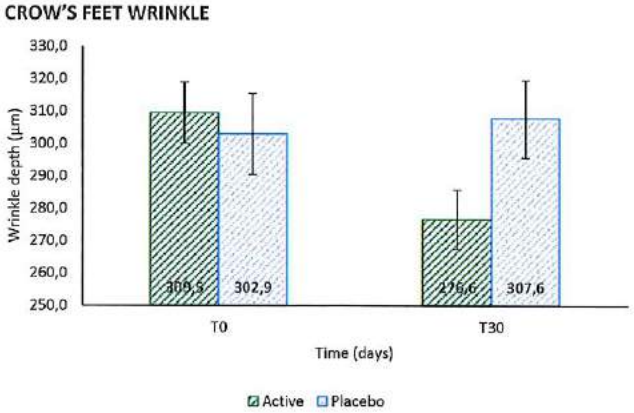
The effect of product in decreasing wrinkles depth is reported in table 11.3.1.1.1 and in graphs 11.3.1.1.2.

Table 11.3.1.1.1. Wrinkles depth. Data are reported as mean ± SEM in µm.

	Active device		Placebo device		Intergroup stat. analysis
	T0	T30	T0	T30	
Crow's feet (µm)	309.5 ± 9.5	276.6 ± 9.2*** (-10.1%)	302.9 ± 12.6	307.6 ± 12.0 (+2.4%)	***
Nasolabial fold (µm)	521.2 ± 22.3	493.7 ± 23.0** (-5.5%)	531.0 ± 20.5	527.6 ± 21.1 (-0.5%)	*
Underneath eye (µm)	241.2 ± 10.0	226.3 ± 10.2*** (-6.5%)	240.5 ± 10.9	242.5 ± 11.1 (+0.8%)	***

In brackets is reported the % variation vs. T0. Beside the figures is reported the intragroup (vs. T0) statistical analysis. Statistical analysis is reported as follows: *, $p < 0.05$ | **, $p < 0.01$, ***, $p < 0.001$.

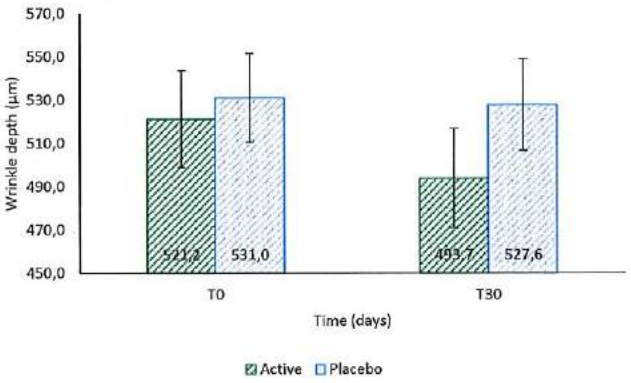
Graph 11.3.1.1.2. The graph shows the obtained results. Data are reported as mean ± SEM.



Comment. The active device determines a statistically significant decrease of the crow's feet wrinkle depth. The % variation vs. T0 (-10.1%) of wrinkle depth is statistically significant compared to the placebo device variation (+2.4%).

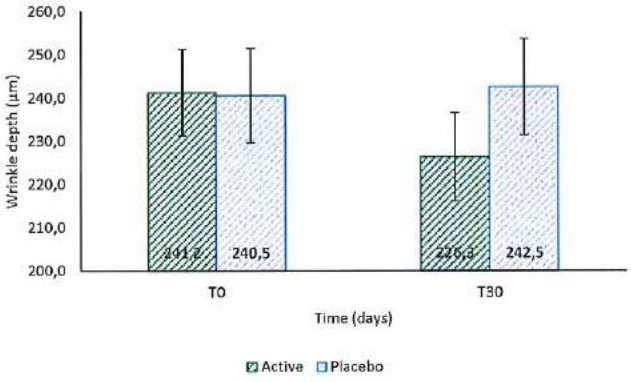
Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

B) NASOLABIAL FOLD



Comment. The active device determines a statistically significant decrease of the nasolabial fold depth. The % variation vs. T0 (-5.5%) of fold depth is statistically significant compared to the placebo device variation (-0.5%).

C) UNDERNEATH EYE WRINKLE



Comment. The active device determines a statistically significant decrease of the underneath eye wrinkle depth. The % variation vs. T0 decrease (-6.5%) of wrinkle depth is statistically significant compared to the placebo device variation (+0.8%).

11.3.1.2. Pores surface

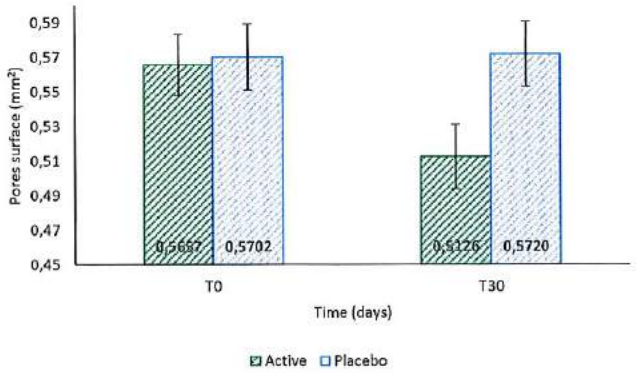
The effect of product in decreasing pores surface is reported in table 11.3.1.2.1 and in graphs 11.3.1.2.2.

Table 11.3.1.2.1. Pores surface. Data are reported as mean ± SEM in mm^2.

	Active device		Placebo device		Intergroup stat. anal.
	T0	T30	T0	T30	
Pores surface (mm^2)	0.5657 ± 0.0177	0.5126 ± 0.0185*** (-9.6%)	0.5702 ± 0.0191	0.5720 ± 0.0188 (+0.5%)	***

In brackets is reported the % variation vs. T0. Beside the figures is reported the intragroup (vs. T0) statistical analysis. Statistical analysis is reported as follows: *, $p < 0.05$ | **, $p < 0.01$, ***, $p < 0.001$.

Graph 11.3.1.2.2. The graph shows the obtained results. Data are reported as mean ± SEM.



Comment. The active device determines a statistically significant decrease of the pores surface. The % variation vs. T0 (-9.6%) of pores surface is statistically significant compared to the placebo device variation (+0.5%).

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

11.3.1.3. Eyebags volume

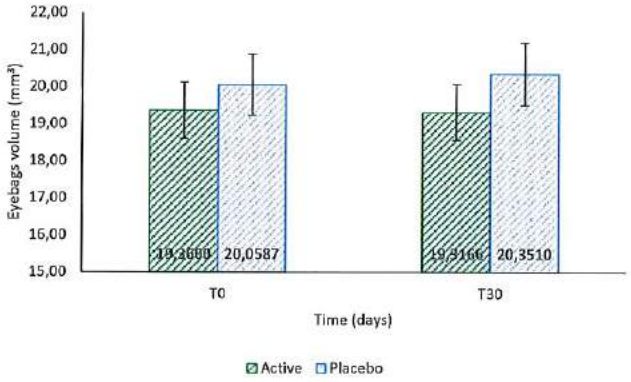
The effect of product on eyebags volume is reported in table 11.3.1.3.1 and in graphs 11.3.1.3.2.

Table 11.3.1.3.1. Eyebags volume. Data are reported as mean ± SEM in mm^3.

	Active device		Placebo device		Intergroup stat. anal.
	T0	T30	T0	T30	
Eyebags volume (mm^3)	19.3600 ± 0.7560	19.3166 ± 0.7587 (+0.4%)	20.0587 ± 0.8252	20.3510 ± 0.8507 (+1.5%)	n.s.

In brackets is reported the % variation vs. T0. Beside the figures is reported the intragroup (vs. T0) statistical analysis. Statistical analysis is reported as follows: n.s., not statistically significant | *, $p < 0.05$ | **, $p < 0.01$, ***, $p < 0.001$.

Graph 11.3.1.3.2. The graph shows the obtained results. Data are reported as mean ± SEM.



Comment. The variation of eyebags volume is not statistically significant neither for the active device nor for the placebo device.

11.3.1.4. Skin moisturization

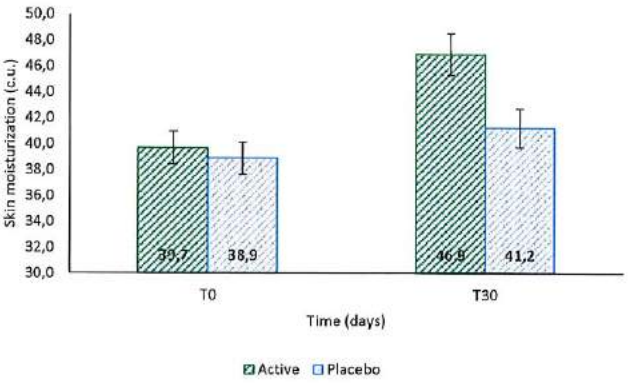
The effect of product on skin moisturization is reported in table 11.3.1.4.1 and in graphs 11.3.1.4.2.

Table 11.3.1.4.1. Skin moisturization. Data are reported as mean ± SEM in corneometric units (c.u.).

	Active device		Placebo device		Intergroup stat. anal.
	T0	T30	T0	T30	
Skin moisturization (c.u.)	39.7 ± 1.3	46.9 ± 1.6*** (+18.1%)	38.9 ± 1.2	41.2 ± 1.5*** (+5.5%)	***

In brackets is reported the % variation vs. T0. Beside the figures is reported the intragroup (vs. T0) statistical analysis. Statistical analysis is reported as follows: n.s., not statistically significant | *, $p < 0.05$ | **, $p < 0.01$, ***, $p < 0.001$.

Graph 11.3.1.4.2. The graph shows the obtained results. Data are reported as mean ± SEM.



Comment. The active device determines a statistically significant increase of the skin moisturization. The % variation vs. T0 (+18.1%) of skin moisturization is statistically significant compared to the placebo device variation (+5.5%).

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

11.3.1.5. Skin radiance

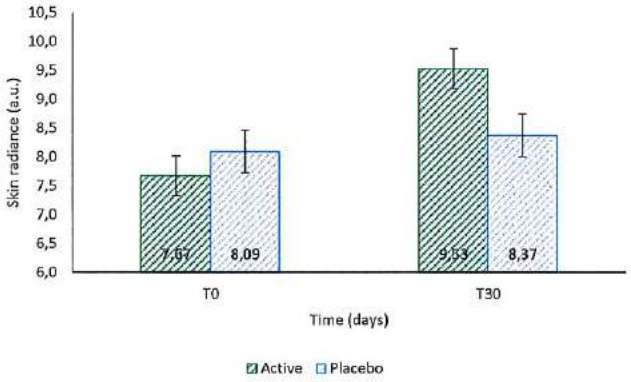
The effect of product on skin radiance is reported in table 11.3.1.5.1 and in graphs 11.3.1.5.2.

Table 11.3.1.5.1. Skin radiance. Data are reported as mean ± SEM in arbitrary units (a.u.).

	Active device		Placebo device		Intergroup stat. anal.
	T0	T30	T0	T30	
Skin radiance (a.u.)	7.67 ± 0.34	9.53 ± 0.35*** (+27.8%)	8.09 ± 0.37	8.37 ± 0.37** (+3.8%)	***

In brackets is reported the % variation vs. T0. Beside the figures is reported the intragroup (vs. T0) statistical analysis. Statistical analysis is reported as follows: n.s., not statistically significant | *, $p < 0.05$ | **, $p < 0.01$, ***, $p < 0.001$.

Graph 11.3.1.5.2. The graph shows the obtained results. Data are reported as mean ± SEM.



Comment. The active device determines a statistically significant increase of the skin radiance. The % variation vs. T0 (+27.8%) of skin radiance is statistically significant compared to the placebo device variation (+3.8%).

11.3.1.6. Skin elasticity

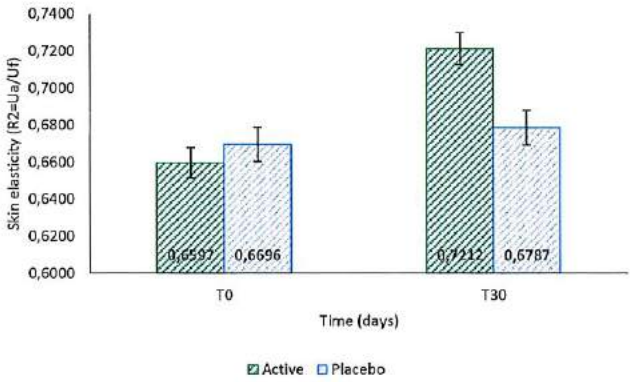
The effect of product on skin radiance is reported in table 11.3.1.6.1 and in graphs 11.3.1.6.2.

Table 11.3.1.6.1. Skin elasticity. Data are reported as mean ± SEM in arbitrary units (a.u.).

	Active device		Placebo device		Intergroup stat. anal.
	T0	T30	T0	T30	
Skin elasticity (R2 = Ua/Uf)	0.6597 ± 0.0082	0.7212 ± 0.0087*** (+9.5%)	0.6696 ± 0.0092	0.6787 ± 0.0093*** (+1.4%)	***

In brackets is reported the % variation vs. T0. Beside the figures is reported the intragroup (vs. T0) statistical analysis. Statistical analysis is reported as follows: n.s., not statistically significant | *, $p < 0.05$ | **, $p < 0.01$, ***, $p < 0.001$.

Graph 11.3.1.6.2. The graph shows the obtained results. Data are reported as mean ± SEM.



Comment. The active device determines a statistically significant increase of the skin elasticity. The % variation vs. T0 (+9.5%) of skin elasticity is statistically significant compared to the placebo device variation (+1.4%). The increase of skin elasticity is correlated to an increase of skin firmness.

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

11.3.1.7. Clinical analysis

The effect of product on wrinkledness, eyebags, and global skin appearance is reported in table 11.3.1.7.1.

Table 11.3.1.7.1. Clinical analysis. Data are reported as % of subjects who had an improvement.

	Active device	Placebo device	Intergroup stat. anal.
Wrinkledness on neck	27.9%	0.0%	***
Wrinkledness on face	48.8%	7.3%	***
Appearance of eyebags	20.9%	4.9%	*
Global appearance of the skin	76.7%	12.2%	***

11.3.1.8. Self-assessment questionnaire

Self-assessment questionnaire answers are reported in table 11.3.1.8.1.

Table 11.3.1.8.1. Self-assessment questionnaire. Data are reported as % of subjects.

		Active		Placebo		Intergroup
no.	Item	Yes	No	Yes	No	stat. anal.
01	Was DermaWand easy to use?	95,3%	4,7%	85,4%	14,6%	n.s.
02	Does your face look/feel younger?	83,7%	16,3%	56,1%	43,9%	**
03	Do you feel the appearance of your skin has improved?	90,7%	9,3%	68,3%	31,7%	*
04	Does your face feel tighter?	83,7%	16,3%	58,5%	41,5%	*
05	Do your wrinkles appear less prominent?	65,1%	34,9%	56,1%	43,9%	n.s.
06	Does your face look more radiant?	81,4%	18,6%	70,7%	29,3%	n.s.
07	Does your skin feel moister?	83,7%	16,3%	63,4%	36,6%	*
08	Do you feel the bags under your eyes are less noticeable?	60,5%	39,5%	31,7%	68,3%	**
09	Do you feel your skin's complexion looks more even?	76,7%	23,3%	63,4%	36,6%	n.s.
10	Does your skin feel rejuvenated?	83,7%	16,3%	58,5%	41,5%	*
11	Does your skin look healthier?	79,1%	20,9%	75,6%	24,4%	n.s.
12	Does your skin look smoother?	88,4%	11,6%	78,0%	22,0%	n.s.
13	Does your skin feel less dry?	81,4%	18,6%	56,1%	43,9%	*
14	Do your eyelid and eyebrows look more lifted?	51,2%	48,8%	19,5%	80,5%	**
15	Does the area around your eyebrow look tighter?	60,5%	39,5%	36,6%	63,4%	*
16	Do you feel your wrinkles are less noticeable?	67,4%	32,6%	58,5%	41,5%	n.s.
17	Do you feel your crow's feet are less noticeable?	65,1%	34,9%	61,0%	39,0%	n.s.
18	Do you feel there has been a reduction in puffiness?	67,4%	32,6%	31,7%	68,3%	**
19	Does your face feel more refreshed and stimulated?	83,7%	16,3%	61,0%	39,0%	*
20	Do you feel your skin tone has improved?	88,4%	11,6%	58,5%	41,5%	**
21	Do you feel there has been an increase in circulation?	67,4%	32,6%	51,2%	48,8%	n.s.
22	Do you feel that the "folds" of your skin have been reduced?	74,4%	25,6%	43,9%	56,1%	**
23	Do you feel like the lines on your forehead have been reduced?	51,2%	48,8%	46,3%	53,7%	n.s.
24	Do you feel you look 10 years younger?	14,0%	86,0%	4,9%	95,1%	n.s.
25	Does your skin appear more-even toned?	86,0%	14,0%	65,9%	34,1%	*
26	Does the skin on your neck appear tighter?	72,1%	27,9%	36,6%	63,4%	**
27	Do you notice any improvement in your facial complexion?	95,3%	4,7%	75,6%	24,4%	**
28	Does your skin feel more alive?	81,4%	18,6%	70,7%	29,3%	n.s.
29	Would you recommend DermaWand to your friends?	88,4%	11,6%	56,1%	43,9%	***

n = 43 for active device

n = 41 for placebo device

11.3.2. Interim analysis

Not applicable.

11.3.3. Tabulation of individual response data

Individual response data are reported in attachment 15.7.

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

12. SAFETY EVALUATION

12.1. Adverse event

Two subjects experienced headache. It was not possible to assess the correlation between product use and the adverse event.

13. DISCUSSION AND OVERALL CONCLUSION

DermaWand® use determines the following results:

Skin parameter	Variation vs. T0
Crow's feet wrinkle depth	-10.1%
Nasolabial fold depth	-5.5%
Underneath eye wrinkle depth	-6.5%
Pores Surface	-9.6%
Eyebags volume	+0.4%
Skin moisturization	+18.1%
Skin radiance	+27.8%
Skin elasticity	+9.5%
Wrinkledness on neck	27.9%*
Wrinkledness on face	48.8%*
Appearance of eyebags	20.9%*
Global appearance of the skin	76.7%*

Data are reported as % variation vs. T0 except for clinical analysis (*) that are reported as % of subjects who had an improvement.

Two subjects experienced headache. It was not possible to assess the correlation between product use and the adverse event.

Investigator signature

Name: Enza Cestone Signature DOTT.SSA ENZA CESTONE MEDICO CHIRURGO SPECIALISTA IN DERMATOLOGIA E VENEREOLOGIA Via Moruzzi, 13/A 27100 PAVIA P.IVA 02341110183 C.F. CST NZE 60C47 M109Z Parere OdM PV n. 32 del 03/11/2009 Date: 10/12/2014 1st issue, 18/05/2015 1st revision, 23/06/2015 2nd revision, 20/11/2017 3rd revision, 21/12/2017 4th revision

Study Director signature

Name: Vincenzo Nobile Signature Date: 10/12/2014 1st issue, 18/05/2015 1st revision, 23/06/2015 2nd revision, 20/11/2017 3rd revision, 21/12/2017 4th revision

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

14. QUALITY ASSURANCE STATEMENT

This study was monitored by the study director. No deviations from study protocol have been found. All the subject enrolled in the study were compliant to study protocol requests.

Study Director signature

Name: Vincenzo Nobile Signature  Date: 10/12/2014 1st issue 18/05/2015 1st revision 23/06/2015 2nd revision 20/11/2017 3rd revision 21/12/2017 4th revision

The results of the study mentioned in this report refer only to the tested products and to the specific experimental conditions of the study. This report or parts of it can be reproduced only with consent of Farcoderm srl. A copy of this report is kept on file at Farcoderm srl. Informed consent form and study documentation are kept on file at Farcoderm srl for 10 years after the date of issue of the report.

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

15 ATTACHMENTS

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

15.1.1 Ethical Committee Approval

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

COPY OF THE ORIGINAL

Comitato Etico Indipendente per le Indagini Cliniche Non Farmacologiche

Società Scientifica Italiana per le Indagini Cliniche Non Farmacologiche
Via XX Settembre 30/4 – 16121 Genova
Partita IVA 01942790997

Rif. 2013/04

Oggetto: **Parere etico** espresso **per un'indagine clinica non farmacologica dal titolo:**

"Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®): double blind, randomized clinical trial of efficacy and safety"
Prot. no.: FU.04.C.I_2013 GCP01

Relativamente all'indagine in oggetto, a seguito della valutazione della documentazione fornita dal promotore discussa nella seduta del 17 Dicembre 2013, questo Comitato Etico esprime, a maggioranza, il seguente giudizio:

Parere Favorevole

Questo Comitato Etico ricorda al **promotore la sottoscrizione da parte di** quest'ultimo a condurre l'indagine in oggetto sotto la propria completa **responsabilità e che il Comitato Etico** e i suoi membri si intendono estranei dal punto di vista operativo, amministrativo, contrattuale, giuridico, economico ed assicurativo,alle modalità attraverso le quali il promotore condurrà l'indagine ed alla scelta dei soggetti (operatori o strutture sanitarie) che saranno coinvolti a qualsiasi titolo in detta indagine.

Genova, 17/12/2013

Il Presidente
del Comitato Etico Indipendente
per le Indagini Cliniche Non Farmacologiche
Dott.ssa Elena Besio

Documentazione esaminata:

1. Protocollo. Final version n. 2 02/12/13
2. Sinossi

Comitato Etico Indipendente per le Indagini Cliniche Non Farmacologiche

Società Scientifica Italiana per le Indagini Cliniche Non Farmacologiche
Via XX Settembre 30/4 – 16121 Genova
Partita IVA 01942790997

COPY OF THE ORIGINAL

Rif. 2014/02

Oggetto: **Parere etico espresso per un'indagine clinica non farmacologica dal titolo:**

"Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®): double blind, randomized clinical trial of efficacy and safety"
Prot. no.: FU.04.C.L_2013 GCP01

Protocol amendment no. 1 (Emendamento al Protocollo approvato nella seduta del 17 dicembre 2013)
Protocol final version no. 3 - 20 January 2014

Relativamente all'indagine in oggetto, a seguito della valutazione della documentazione fornita dal promotore discussa nella seduta del **6 febbraio 2014**, questo Comitato Etico esprime, all'unanimità, il seguente giudizio:

Parere Favorevole

Con la presente si segnala che nel documento *Protocol Amendment no. 1* la versione finale del protocollo è indicata come no. 3 - 17 January 2014 e non *no. 3 - 20 January 2014.*

Questo Comitato Etico ricorda al promotore la sottoscrizione da parte di quest'ultimo a condurre l'indagine in oggetto sotto la propria completa responsabilità e che il Comitato Etico e i suoi membri si intendono estranei dal punto di vista operativo, amministrativo, contrattuale, giuridico, economico ed assicurativo,alle modalità attraverso le quali il promotore condurrà l'indagine ed alla scelta dei soggetti (operatori o strutture sanitarie) che saranno coinvolti a qualsiasi titolo in detta indagine.

Genova, 06/02/2014

Il Presidente
del Comitato Etico Indipendente
per le Indagini Cliniche Non Farmacologiche
Dott.ssa Elena Besio

Documentazione esaminata:

Protocol amendment no. 1

Protocol final version no. 3 - 20 January 2014

15.1.2 Informed Consent Form

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

Farcoderm TESTED WELLNESS

CONSENSO INFORMATO

Numero dello studio: FU.04.C.L_2013/GCP01

Vers. 3.0 del 28.01.2014

Titolo dello studio: **VALUTAZIONE CLINICO STRUMENTALE DELL'EFFICACIA DI UN DISPOSITIVO ESTETICO (DERMAWAND®): STUDIO CLINICO DELL'EFFICACIA E DELLA SICUREZZA IN DOPPIO CIECO E RANDOMIZZATO**

Cognome e nome: _____

Indirizzo: _____

Gentile Signora, con la presente la invitiamo a prendere parte ad uno studio di ricerca. Prima che Lei decida di partecipare, è importante che Lei capisca perché viene fatto questo studio e cosa comporterà. Per favore, legga attentamente le informazioni qui di seguito riportate e ne discuta con altri, se preferisce e/o lo ritiene opportuno. Chieda informazioni al responsabile dello studio se qualcosa non Le risultasse chiaro o se volesse avere maggiori informazioni. Lei è libera di accettare o di rifiutare a partecipare a questo studio.
Per la durata dello studio sarà seguita dalla dottoressa Enza Cestone (medico dermatologo) e dai suoi collaboratori.

INFORMAZIONI E SCOPO DELLO STUDIO

Lo scopo di questo studio di ricerca, sponsorizzato da un nostro cliente nel settore cosmetico, è valutare l'efficacia del dispositivo estetico Dermawand. Lo studio si svolgerà presso Farcoderm, Via Angelini 21,27028 San Martino Siccomario (PV).
Dermawand® è un dispositivo estetico registrato come dispositivo medico di classe I negli USA, come dispositivo per l'igiene e la cosmesi e come dispositivo estetico in Europa. Il dispositivo emette onde corrente ad alta frequenza e a basso livello e si propone di attenuare i segni dell'invecchiamento cutaneo.
Lo studio viene condotto contro placebo ed è possibile che Lei sia assegnata al gruppo di trattamento placebo.
Si prevede di reclutare 110 volontarie sane. La durata dello studio è di 30 giorni.
L'impegno a Lei richiesto è di circa 30 minuti per visita per un totale di 3 visite, come segue:

- ✓ Visita 1* (screening), sarà valutata la sua idoneità a partecipare allo studio
- ✓ Visita 2* (arruolamento/inizio studio), se lo sperimentatore giudica la sua idoneità a partecipare allo studio Lei sarà arruolata nello studio e lo sperimentatore misurare lo stato della sua pelle mediante tecniche non invasive
- ✓ Visita 3 (fine trattamento), lo sperimentatore acquisirò lo stato della sua pelle a distanza di 30 giorni di trattamento mediante tecniche non invasive.

Ad ogni controllo le chiediamo di recarsi presso i nostri laboratori a pelle pulita e almeno 8 ore dopo l'ultimo utilizzo del prodotto/cosmetico.
* le visite 1 e 2 possono coincidere, limitando così l'impegno a lei richiesto a 2 visite della durata di circa 30 minuti ciascuna.

PROCEDURE DELLO STUDIO

Se Lei accetta di partecipare allo studio, Le verrà chiesto di effettuare le seguenti visite:

Visita 1, di screening
Durante la visita, verrà applicata la seguente procedura:

- firma del modulo di consenso informato
- registrazione dei suo dati demografici
- verifica della sua idoneità a partecipare allo studio

Al termine della visita di screening, se Lei sarà ritenuta idonea a partecipare allo studio, sarà fissato la data per la visita di inizio studio. Le sarà, inoltre, ricordato di rispettare le restrizioni dello studio

Visita 2, di arruolamento/inizio studio
Durante la visita, verrà applicata la seguente procedura:

- Verifica/Conferma della sua idoneità a partecipare allo studio
- misura dello stato della sua pelle.

Visita 3, fine trattamento
Durante la visita, verrà applicata la seguente procedura:

- misura dello stato della sua pelle
- consegna del prodotto

Farcoderm srl
Sede operativa: Via Angelini, 21 - 27028 San Martino Siccomario (PV)
Sede legale: Piazzale Siena 11 - 20146 (MI) - C.F. - P.iva 03893350961
Tel. 0382 25504 - Fax 0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

Farcoderm TESTED WELLNESS

CONSENSO INFORMATO

Numero dello studio:
FU.04.C.L_2013/GCP01

Vers. 3.0 del 28.01.2014

RESTRIZIONI E PROIBIZIONI

Ad ogni controllo le chiediamo di recarsi presso i nostri laboratori a pelle pulita e almeno 8 ore dopo l'ultimo utilizzo del prodotto/cosmetico.

RISCHI DERIVANTI DALLO STUDIO

I rischi associati alle procedure utilizzate in questo studio sono giudicati molto bassi. Le tecniche utilizzate per la misura dello stato della sua pelle non sono invasive e non presentano rischi.
DermaWand® è un dispositivo già presente sul mercato dal 1998. Il prodotto è stato valutato come sicuro da organismi di certificazione indipendenti ed è registrato come dispositivo medico di classe I negli USA, come dispositivo per l'igiene e la cosmesi e come dispositivo estetico in Europa.
In caso di insorgenza di reazione avversa La invitiamo a contattare il centro sperimentatore al n° 0382 25504.

BENEFICI DERIVANTI DALLO STUDIO

È possibile che alla fine del trattamento lei possa notare un miglioramento della pelle del suo viso (riduzione rugosità, borse palpebrali, aumento della luminosità cutanea e/o un miglioramento in generale dell'aspetto estetico della pelle).

INCENTIVI FINANZIARI:

Se Lei viene selezionata per lo studio le verrà pagata una somma totale di € 25,00 (tasse incluse). Il pagamento verrà effettuato per la completa partecipazione alla fine dello studio per coprire le spese di viaggio,tempo e sforzo. Qualora quando non riuscisse a completare lo studio Le verrà pagata la cifra di € 12,50 (tasse incluse) per ciascun visita portata a termine.

CONFIDENZIALITÀ

Le sue informazioni relative a questo studio saranno archiviate in regime di confidenzialità (per almeno 10 anni). Le seguenti persone avranno accesso all'archivio del suo studio:

- Sperimentatore dello studio ed il suo staff (tutti i documenti dello studio)
- Azienda sponsor (moduli dei criteri di inclusione, non inclusione, scheda raccolta dati, database elettronico)
- Monitor dello studio (tutti i documenti dello studio)
- Altri uffici governativi (tutti i documenti dello studio)

Ai sensi dell'articolo 13 del D.Lgs. 196/2003 (Codice in materia di protezione dei dati personali), La informiamo che i suoi dati personali e le informazioni derivanti dagli studi clinici e riguardanti la sua salute, da lei liberamente forniti, verranno utilizzate nel rispetto della riservatezza ai fini dello svolgimento di studi con lo scopo di determinare l'efficacia di specifici prodotti cosmetici/integratori alimentari. Qualora i risultati delle ricerche dovessero essere pubblicati o diffusi in convegni o riviste scientifiche, ciò avverrà in modo totalmente anonimo. In relazione all'informativa che mi avete fornito ex art. 13 del D.L.gs. 196/2003 esprimo il mio consenso, ai sensi e per gli effetti dell'art. 23 della menzionata legge, al trattamento secondo le modalità e per gli scopi comunicatimi dei dati personali da me forniti e di quelli che in futuro fornirò o che comunque si produrranno durante il rapporto con Farcoderm srl. Accetto che i dati registrati durante gli studi possano essere soggetti a trattamento computerizzato da parte del ricercatore, ma sono a conoscenza che qualsiasi informazione che possa identificarmi sarà tenuta confidenziale nelle registrazioni dello studio.
Dal suo canto Lei dovrebbe tenere le informazioni inerenti questo studio e date da Farcoderm, confidenziali e non deve divulgarle a terzi. Anche se Lei interrompe lo studio prematuramente, i suoi dati potrebbero essere utilizzati nell'analisi. Gli obblighi spiegati in questo paragrafo proseguono anche dopo il termine dello studio.

ASSICURAZIONE

La sua partecipazione a questo studio è coperta da un contratto di assicurazione che assicura la responsabilità civile dello Sponsor (per ogni evento/reazione avversa causata dal prodotto).

CONTATTI

Lei può fare domande relative allo studio in ogni momento. Se ha domande o preoccupazioni circa il trattamento, o se si verifica un incidente connesso allo studio, per favore contatti:

- La dr.ssa Enza Cestone al numero di telefono: 0382 25504
- il dr. Vincenzo Nobile al numero di telefono: 0382 25504.

Farcoderm srl
Sede operativa: Via Angelini, 21 - 27028 San Martino Siccomario (PV)
Sede legale: Piazzale Siena 11 - 20146 (MI) - C.F. - P.iva 03893350961
Tel. 0382 25504 - Fax 0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Azienda con sistema di gestione qualità UNI EN ISO 9001:2008 certificato da Certiquality S.r.l.

Farcoderm TESTED WELLNESS

CONSENSO INFORMATO

Numero dello studio:
FU.04.C.L_2013/GCP01

Vers. 3.0 del 28.01.2014

CONCLUSIONI SIGNIFICATIVE DELLO STUDIO

Lei verrà informata di tutti i dati significativi scoperti durante il corso dello studio e che possono influenzare la sua disponibilità a continuare a partecipare.

PARTECIPAZIONE DEL VOLONTARIO/RITIRO

La sua partecipazione è volontaria, e Lei può rifiutare di partecipare o può firmare il consenso e non continuare la partecipazione allo studio in qualunque momento senza conseguenze penali o sospensione di benefici ai quali ha già diritto. Lo sperimentatore potrebbe interrompere la sua partecipazione in questo studio in qualunque momento dopo averle spiegato le ragioni della sospensione del trattamento. In questo caso lo Sperimentatore continuerà a fornirLe le cure necessarie, se ritenuto opportuno.
Il consenso informato potrebbe aver bisogno di essere revisionato durante lo studio se nuove informazioni acquisite relativamente alla sicurezza del prodotto in esame potessero influenzare la sua salute, benessere o volontà di rimanere in questo studio. Lo sperimentatore Le parlerà di questo e discuterà con Lei la sua volontà a continuare la sua partecipazione allo studio. Se lei decide di continuare lo studio, Le verrà chiesto di firmare un consenso informato aggiornato. D'altro lato, tenendo conto di queste nuove informazioni, lo sperimentatore potrebbe considerare il suo interesse per sospendere lo studio.

LESIONI CONNESSE ALLA RICERCA

Lo sperimentatore provvederà a una cura continuata per ogni lesione connessa allo studio,senza nessun costo per Lei (e il tutto pagato dall'assicurazione dello sponsor).

RISARCIMENTO DI INFORTUNI CONNESSI ALLA RICERCA

Se Lei dovesse subire degli infortuni derivanti dalla partecipazione a questo studio, Le saranno somministrate le necessarie cure mediche da parte dello sperimentatore (e il tutto pagato dall'assicurazione dello Sponsor).

DICHIARAZIONI DELLO STATO DI BUONA SALUTE

La invitiamo adesso a prendere nota e a sottoscrivere quanto sotto riportato.

|_| Dichiaro di non essere in stato di gravidanza o allattamento
|_| Dichiaro di non essere portatore di pacemaker o di defibrillatore interno o di altri dispositivi metallici impiantabili o elettronici
|_| Dichiaro di non essere portatore di impianto permanente nella zona trattata come piastre metalliche e viti o silicone, a meno che queste non siano abbastanza profonde nel piano periostale
|_| Dichiaro di non aver fatto ricorso a iniezioni di Botox, acido ialuronico, collagene, grasso o altri metodi riempitivi con biomateriali a livello intradermico o sub-dermico superficiale
|_| Dichiaro di non soffrire e/o di aver sofferto di cancro cutaneo, o altri tipi di cancro o nei precancerosi
|_| Dichiaro di non soffrire di patologie severe concomitanti come ad esempio patologie cardiache
|_| Dichiaro di non soffrire e/o di aver sofferto di compromissione del sistema immunitario dovuto a malattie immunosoppressive come l'AIDS, o all'uso di farmaci immunosoppressivi
|_| Dichiaro di non soffrire e/o di aver sofferto, nell'area del test, di patologie quali l'Herpes simplex, piaghe, lesioni attive, psoriasi, eczema ed eruzioni cutanee
|_| Dichiaro di non soffrire e/o di aver sofferto di alterazioni cutanee, come ad esempio: cheloidi, guarigione delle ferite anomale, pelle fragile
|_| Dichiaro di non soffrire e/o di aver sofferto di coagulopatie e/o di non aver fatto uso di anticoagulanti negli ultimi dieci giorni
|_| Dichiaro di non aver effettuato interventi di chirurgia estetica nei 12 mesi precedenti lo studio
|_| Dichiaro di non aver effettuato interventi di dermoabrasione, ringiovanimento facciale o peeling chimici profondi
|_| Dichiaro di non aver effettuato utilizzo di dispositivi a luce, a luce laser o ad altra frequenza o di altri dispositivi nei 6 mesi precedenti lo studio
|_| Dichiaro di non essere in cura con isotretinoina (Accutane® o simili) nei 6 mesi precedenti lo studio

Farcoderm srl
Sede operativa: Via Angelini, 21 - 27028 San Martino Siccomario (PV)
Sede legale: Piazzale Siena 11 - 20146 (MI) - C.F. - P.iva 03893350961
Tel. 0382 25504 - Fax 0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Azienda con sistema di gestione qualità UNI EN ISO 9001:2008 certificato da Certiquality S.r.l.

Farcoderm TESTED WELLNESS

CONSENSO INFORMATO

Numero dello studio:
FU.04.C.L_2013/GCP01

Vers. 3.0 del 28.01.2014

La mia firma indica che:

- ✓ Ho letto e capito tutte le informazioni scritte sopra.
- ✓ Ho discusso le mie domande col medico dello studio e lo staff
- ✓ Riceverò una copia firmata del consenso informato.
- ✓ Sono volontariamente d'accordo a partecipare a questo studio.
- ✓ Di essere consapevole della mia responsabilità, nel caso di dichiarazioni non veritiere e falsità
- ✓ Ho il diritto di non aderire allo studio o di ritirarmi in qualsiasi momento lo lo desideri.
- ✓ Autorizzo la pubblicazione dei miei dati, allo sponsor e alle autorità competenti.
- ✓ Autorizzo l'uso dei risultati ottenuti per qualsiasi pubblicazione scientifica. In qualunque caso la privacy dei miei dati personali sarà tenuta in confidenzialità.
- ✓ Firmando questo consenso informato, io non rinuncio a nessun diritto legale.

Sono consapevole di essere libero/di ritirare il mio consenso a partecipare a questo studio e di interrompere la mia partecipazione in qualunque momento. Inoltre sono d'accordo di informare il ricercatore di ogni cambiamento nel mio stato di salute o medicazione che potrebbe occorrermi durante il periodo di studio.
Mi impegno a non partecipare a studi analoghi nello stesso periodo di tempo.

Ai sensi dell'articolo 13 del D.Lgs. 196/2003 (Codice in materia di protezione dei dati personali), La informiamo che i suoi dati personali e le informazioni derivanti dagli studi clinici e riguardanti la sua salute, da lei liberamente forniti, verranno utilizzate nel rispetto della riservatezza ai fini dello svolgimento di studi con lo scopo di determinare l'efficacia di specifici prodotti cosmetici/dispositivi estetici. Qualora i risultati delle ricerche dovessero essere pubblicati o diffusi in convegni o riviste scientifiche, ciò avverrà in modo totalmente anonimo. In relazione all'informativa che mi avete fornito ex art. 13 del D.L.gs. 196/2003 esprimo il mio consenso, ai sensi e per gli effetti dell'art. 23 della menzionata legge, al trattamento secondo le modalità e per gli scopi comunicatimi dei dati personali da me forniti e di quelli che in futuro fornirò o che comunque si produrranno durante il rapporto con Farcoderm srl. Accetto che i dati registrati durante gli studi possano essere soggetti a trattamento computerizzato da parte del ricercatore, ma sono a conoscenza che qualsiasi informazione che possa identificarmi sarà tenuta confidenziale nelle registrazioni dello studio.

Posso chiedere altre informazioni circa lo studio o l'insorgenza di reazioni avverse, in qualunque momento telefonando al direttore dello studio al numero 0382 25504.

La sottoscritta .....(nome e cognome, in stampatello)
ACCONSENTE di prendere parte allo studio sperimentale che mi è stato descritto e che sarà condotto dal dr. Enza Cestone.

Ho letto e firmato questa dichiarazione di consenso pienamente a conoscenza delle procedure dello studio.

Data (gg/mm/anno) Firma del volontario

|_|_| / |_|_| / |_|_|_|_| _____

Confermo che il volontario ha letto il titolo,lo scopo e le informazioni inerenti allo studio. Al volontario è stata data l'opportunità di fare domande e le domande sono state esaurienti: lo scopo, i termini e le caratteristiche, i benefici e i possibili effetti collaterali derivanti dallo studio sono stati spiegati al volontario. Il volontario, informato, ha acconsentito a prendere parte a questo studio

Data (gg/mm/anno) Nome e cognome dell'Sperimentatore (stampatello) Firma dello Sperimentatore

|_|_| / |_|_| / |_|_|_|_| _____ _____

Farcoderm srl
Sede operativa: Via Angelini, 21 - 27028 San Martino Siccomario (PV)
Sede legale: Piazzale Siena 11 - 20146 (MI) - C.F. - P.iva 03893350961
Tel. 0382 25504 - Fax 0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

15.1.3 Case Report Form

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

"Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®): double blind, randomized clinical trial of efficacy and safety"

CODICE SOGGETTO (VOL. ID)					

(Vedi, software gestione volontari)

NUMERO DI SCREENING			
S			

NUMERO DI RANDOMIZZAZIONE			
R			

FARCODERM SRL
Via Angelini, 21
27028 San Martino Siccomario (PV)

Sperimentatore	Dr. Enza Cestone, Medico Dermatologo
Direttore dello studio, QC	Dr. Vincenzo Nobile

Istruzioni per la compilazione

1. Scrivere in modo chiaro utilizzando una penna a sfera di colore blue.

2. Compilare la CRF in tutte le sue parti. Le seguenti abbreviazioni devono essere utilizzate, dove appropriato, anziché lasciare uno spazio in bianco:

   "UNK" = Non noto "ND" = Non fatto "NA" = Non applicabile

3. Il formato della data deve essere il seguente: GG-MM-AAAA ("giorno-mese-anno").

4. Il formato dell'ora deve essere nel formato 24 ore (formato militare). Ad esempio, 9:00 AM deve essere scritto come 09:00 mentre 9:00 PM deve essere scritto come 21:00.

5. Qualsiasi errore o correzione deve essere fatta barrando il dato originale con una linea singola che non copra lo stesso. Qualsiasi correzione deve essere fatta il più vicino possibile al dato originale (errato/non corretto). Qualsiasi correzione deve essere datata e siglata dalla persona che ha fatto la correzione. Non cancellare o utilizzare il bianchetto.

6. Nel caso in cui si scelga "Altro" come risposta, indicare il motivo della risposta.

VISITA (-1): VISITA DI SCREENING

DATA DELLA VISITA : | | | - | | | - | 2 | 0 | 1 | 4 |
gg mm aaaa

CONSENSO INFORMATO

Il soggetto ha letto, compreso e firmato il consenso informato prima che sia stata intrapresa qualsiasi procedura correlata allo studio? ☐ SI ☐ NO

Data di firma del consenso informato : _____-_____-2014
gg mm aaaa

DEMOGRAFIA

Data di nascita: _____-_____-_____(gg-mm-aaaa) Età: _____ anni (30-70 anni)

Sesso: ☐ F ☐ M

Razza: ☐ Caucasica ☐ Nera ☐ Asiatica ☐ Altro _____ (specificare)

Menopausa: ☐ SI ☐ NO

Tabagismo: ☐ SI ☐ NO

Consumo di alcolici: ☐ SI ☐ NO

TIPOLOGIA CUTANEA

☐ CRONOINVECCHIAMENTO ☐ FOTOINVECCHIAMENTO

METODO CONTRACCETTIVO UTILIZZATO

☐ Astinenza
☐ Dispositivo intrauterino (IUD)
☐ Impianto
☐ Profilattico
☐ Contraccettivo orale
☐ Patch
☐ Iniezione
☐ Altro metodo, specificare: |_____|

I soggetti aventi le caratteristiche evidenziate in grigio non sono da arruolare

VISITA (-1): VISITA DI SCREENING

STORIA MEDICA (relativa a condizioni di interesse dermatologico)				
Condizione, Diagnosi o Procedura chirurgica ☐ Nessuna	Data di inizio gg-mm-aaaa	Data di fine gg-mm-aaaa o C Indicare "C" se la condizione è ancora in corso		Trattamento farmacologico concomitante
1	____-____-____	____-____-____	☐ C	☐ Si ☐ No
2	____-____-____	____-____-____	☐ C	☐ Si ☐ No
3	____-____-____	____-____-____	☐ C	☐ Si ☐ No

TRATTAMENTI FARMACOLOGICI (ivi inclusa la contraccezione*)					
Nome del farmaco Dose totale e via di somministrazione ☐ Nessuna		Data di inizio gg-mm-aaaa	Data di fine gg-mm-aaaa o C Indicare "C" se la condizione è ancora in corso		Indicazione (indicare il motivo per cui il soggetto è in cura)
NOME	DOSE E VIA				
1		____-____-____	____-____-____	☐ C	☐ Tratt. Cronico ☐ Tratt. Acuto ☐ Tratt. Preventivo ☐ Altro, specificare |_____|
2		____-____-____	____-____-____	☐ C	☐ Tratt. Cronico ☐ Tratt. Acuto ☐ Tratt. Preventivo ☐ Altro, specificare |_____|
3		____-____-____	____-____-____	☐ C	☐ Tratt. Cronico ☐ Tratt. Acuto ☐ Tratt. Preventivo ☐ Altro, specificare |_____|

* Indicare la contracccezione con "Altro" specificazione "contraccezione".

VISITA (-1): VISITA DI SCREENING

N°	VERIFICA CRITERI DI INCLUSIONE	SI	NO
1	Buono stato di salute generale		
2	Sesso femminile		
3	Razza caucasica		
4	Età compresa tra i 30 ed i 70 anni		
5	Rugosità su tutto il viso ("zampe di gallina"/pieghe nasolabiali/rughe palpebrali)		
6	Borse sotto gli occhi		
7	Consenso all'acquisizione di immagini prima e dopo mediante Primos 3D/Macchina fotografica		
8	Impegno a seguire le procedure del trattamento ogni giorno per 30 giorni		
9	Adeguato periodo di riposo tra due trattamenti		
10	Impegno a non utilizzare prodotti antiaging durante tutta la durata dello studio		
11	Impegno a non variare la normale routine quotidiana		
12	Il soggetto è sotto adeguata terapia contraccettiva (orale e non)		

Affinché il soggetto sia eligibile a partecipare allo studio tutte le risposte devono essere "SI"

N°	VERIFICA CRITERI DI NON INCLUSIONE	SI	NO
1	Il soggetto non soddisfa i criteri di inclusione		
2	Diagnosi positiva per atopia o pelle reattiva		
3	Storia pregressa di allergia o suscettibilità ai prodotti cosmetici, toiletries, solari e/o a farmaci topici		
4	Soggetto con condizioni cutanee che lo sperimentatore non ritiene adeguate per la partecipazione allo studio		
5	Pacemaker o defibrillatore interno o altri dispositivi metallici impiantabili o dispositivi elettronici		
6	Impianti permanenti nell'area da sottoporre a trattamento come ad esempio placche o viti metalliche o silicone ad eccezione che questi non siano impiantati abbastanza profondamente nel piano periostale		
7	Aree intradermiche e/o sub-dermiche superficiali sottoposte ad iniezione di botox/acido ialuronico/collagene/grasso o altri metodi riempitivi dei volumi facciali utilizzando biomateriali, negli ultimi sei mesi		
8	Storia pregressa/attuale di cancro cutaneo, o altro tipo di cancro, o nei precancerosi		
9	Condizioni concomitanti severe, come ad esempio patologie cardiache		
10	Gravidanza o allattamento		
11	Compromissione del sistema immunitario dovuta a patologie come l'AIDS e l'HIV o all'uso di farmaci immunosoppressivi		
12	Paziente con storia di patologie stimolate dal calore, come Herpes simplex ricorrente nell'area da sottoporre a trattamento, piaghe, psoriasi, eczema ed eruzioni cutanee		
13	Storia di patologie cutanee, cheloidi, cicatrizzazione alterata, così come cute molto secca e fragile		
14	Storia di coagulopatie o utilizzo di anticoagulanti negli ultimi 10 giorni		
15	Qualsiasi intervento di chirurgia facciale nei 12 mesi precedenti la data di inizio del trattamento		
16	Trattamenti di dermoabrasione, resurfacing, o peeling chimici profondi al viso nei tre mesi precedenti la data di inizio trattamento		
17	Trattamenti a base di luce, laser, radio o ultrafrequenza, o con altri dispositivi nei 6 mesi precedenti la data di inizio del trattamento		
18	Uso di isotretinoina (Accutane®) nei tre mesi precedenti la data di inizio studio		
20	Dipendenza da droghe e da alcool		
21	Soggetto adulto protetto dalla legge (sotto controllo od ospedalizzato in istituzioni pubbliche o private per motivi diversi dalla ricerca, o incarcerato)		
22	Soggetto non capace di comunicare o cooperare con lo sperimentatore per problemi relativi al linguaggio, a ritardo mentale o funzioni cerebrali compromesse		

Affinché il soggetto sia eligibile a partecipare allo studio tutte le risposte devono essere "No"

ELIGIBILITA'
Il soggetto soddisfa tutti i criteri di inclusione nello studio? ☐ SI ☐ NO, spiegare _____ e completare il modulo "Sommario del volontario" riportato alla fine della CRF

Io sottoscritto confermo che il soggetto soddisfa i criteri di inclusione e che allo stesso modo, nessuno dei criteri di non inclusione su riportati sono applicabili.

Data: _____-_____-2014
gg mm aaaa

Nome e cognome dello Sperimentatore: Enza Cestone

Firma dello Sperimentatore _____

VISITA A T0 (PRIMA VISITA)

DATA DELLA VISITA : gg - Mm - 2014 (aaaa)

ORA: hh : Mm

PARAMETRI

Idratazione cutanea (viso):

Elasticità cutanea (R2, guancia):

Primos 3D:

- ☐ Perioculare (zampe di gallina)
- ☐ Perioculare (sottorbitarie)
- ☐ Nasolabiale
- ☐ Borse

Gloss (guancia):

Immagine fotografica:

- ☐ Occhi per analisi d'immagine
- ☐ Viso e collo full-face

Analisi clinica

Area	Score	Ref.
Rughe perioculari (zampe di gallina)		Bazin pag. 41
Rughe fronte		Bazin pag. 43
Rughe glabellari		Bazin pag. 45
Rughe sottorbirtarie		Bazin pag. 49
Rughe nasolabiali		Bazin pag. 51
Rughe perilabiali		Bazin pag. 53
Rughe dell'angolo della bocca		Bazin pag. 55
Rughe del collo		Bazin pag. 59
Borse		Bazin pag. 47

VISITA A T30 (FINE STUDIO)

DATA DELLA VISITA : | | | - | | | - | 2 | 0 | 1 | 4 |
gg Mm aaaa

ORA: | | | : | | |
hh Mm

PARAMETRI

Idratazione cutanea (viso): |

Elasticità cutanea (R2, guancia): |

Primos 3D:
- ☐ Perioculare (zampe di gallina)
- ☐ Perioculare (sottorbitarie)
- ☐ Nasolabiale
- ☐ Borse

Gloss (guancia): |

Immagine fotografica:
- ☐ Occhi per analisi d'immagine
- ☐ Viso e collo full-face

ELIGIBILITA'

Il soggetto soddisfa tutti i criteri di inclusione nello studio?

☐ SI

☐ NO, spiegare _____ e completare il modulo "Sommario del volontario" riportato alla fine della CRF

TRATTAMENTI CONCOMITANTI

☐ Nessun trattamento concomitante

Nome del farmaco Dose totale e via di somministrazione ☐ Nessuno		**Data di inizio** gg-mm-aaaa	**Data di fine** gg-mm-aaaa o C Indicare "C" se la condizione è ancora in corso		**Indicazione** (indicare il motivo per cui il soggetto è in cura)
NOME	DOSE E VIA				
1		_____-_____-_____	_____-_____-_____	☐ C	☐ evento avverso |___| ☐ condizione pre-esistente ☐ Altro, specificare |_____|
2		_____-_____-_____	_____-_____-_____	☐ C	☐ evento avverso |___| ☐ condizione pre-esistente ☐ Altro, specificare |_____|
3		_____-_____-_____	_____-_____-_____	☐ C	☐ evento avverso |___| ☐ condizione pre-esistente ☐ Altro, specificare |_____|
4		_____-_____-_____	_____-_____-_____	☐ C	☐ evento avverso |___| ☐ condizione pre-esistente ☐ Altro, specificare |_____|
5		_____-_____-_____	_____-_____-_____	☐ C	☐ evento avverso |___| ☐ condizione pre-esistente ☐ Altro, specificare |_____|
6		_____-_____-_____	_____-_____-_____	☐ C	☐ evento avverso |___| ☐ condizione pre-esistente ☐ Altro, specificare |_____|
7		_____-_____-_____	_____-_____-_____	☐ C	☐ evento avverso |___| ☐ condizione pre-esistente ☐ Altro, specificare |_____|

EVENTI COSMETICI AVVERSI

☐ Nessun evento cosmetico avverso

Descrizione dell'evento cosmetico avverso	Dettaglio dell'evento e della localizzazione	Data di inizio e di fine gg-mm-aaaa	Intensità	L'evento e correlato a:	Durata
Evento n° |____| |________ ________ ________|		DATA DI INIZIO __-__-__ DATA DI FINE __-__-__	☐ Lieve ☐ Moderato	☐ correlato a*: Prodotto ☐ Protocollo ☐ ☐ Non correlato *☐ Non valutabile	☐ pochi secondi |____| minuti |____| ore |____| giorni
Evento n° |____| |________ ________ ________|		DATA DI INIZIO __-__-__ DATA DI FINE __-__-__	☐ Lieve ☐ Moderato	☐ correlato a*: Prodotto ☐ Protocollo ☐ ☐ Non correlato *☐ Non valutabile	☐ pochi secondi |____| minuti |____| ore |____| giorni
Evento n° |____| |________ ________ ________|		DATA DI INIZIO __-__-__ DATA DI FINE __-__-__	☐ Lieve ☐ Moderato	☐ correlato a*: Prodotto ☐ Protocollo ☐ ☐ Non correlato *☐ Non valutabile	☐ pochi secondi |____| minuti |____| ore |____| giorni
Evento n° |____| |________ ________ ________|		DATA DI INIZIO __-__-__ DATA DI FINE __-__-__	☐ Lieve ☐ Moderato	☐ correlato a*: Prodotto ☐ Protocollo ☐ ☐ Non correlato *☐ Non valutabile	☐ pochi secondi |____| minuti |____| ore |____| giorni
Evento n° |____| |________ ________ ________|		DATA DI INIZIO __-__-__ DATA DI FINE __-__-__	☐ Lieve ☐ Moderato	☐ correlato a*: Prodotto ☐ Protocollo ☐ ☐ Non correlato *☐ Non valutabile	☐ pochi secondi |____| minuti |____| ore |____| giorni

EVENTI AVVERSI

☐ Nessun evento avverso

Descrizione AE	|_______________________________________|
Dettaglio dell'AE (diagnosi e localizzazione)	

N°	Data di inizio e di fine gg-mm-aa	Intensità	Azione intrapresa relativa al prodotto test	Trattamento concomitante	SAE Se si completare il modulo SAE	L'evento è:	Durata
|__|	DATA DI INIZIO ___-___-___ DATA DI FINE ___-___-___	☐ Lieve ☐ Moderato ☐ Severo	☐ Sospeso ☐ Ridotto ☐ Ritardato ☐ Ritardato e ridotto ☐ Non cambiato	☐ Si ☐ No		☐ correlato a*: Prodotto ☐ Protocollo ☐ ☐ Non correlato *☐ Non valutabile	☐ < 1 ora |__| ore |__| giorni
|__|	DATA DI INIZIO ___-___-___ DATA DI FINE ___-___-___	☐ Lieve ☐ Moderato ☐ Severo	☐ Sospeso ☐ Ridotto ☐ Ritardato ☐ Ritardato e ridotto ☐ Non cambiato	☐ Si ☐ No		☐ correlato a*: Prodotto ☐ Protocollo ☐ ☐ Non correlato *☐ Non valutabile	☐ < 1 ora |__| ore |__| giorni
|__|	DATA DI INIZIO ___-___-___ DATA DI FINE ___-___-___	☐ Lieve ☐ Moderato ☐ Severo	☐ Sospeso ☐ Ridotto ☐ Ritardato ☐ Ritardato e ridotto ☐ Non cambiato	☐ Si ☐ No		☐ correlato a*: Prodotto ☐ Protocollo ☐ ☐ Non correlato *☐ Non valutabile	☐ < 1 ora |__| ore |__| giorni
|__|	DATA DI INIZIO ___-___-___ DATA DI FINE ___-___-___	☐ Lieve ☐ Moderato ☐ Severo	☐ Sospeso ☐ Ridotto ☐ Ritardato ☐ Ritardato e ridotto ☐ Non cambiato	☐ Si ☐ No		☐ correlato a*: Prodotto ☐ Protocollo ☐ ☐ Non correlato *☐ Non valutabile	☐ < 1 ora |__| ore |__| giorni

DA COMPLETARE ALLA FINE DELLO STUDIO

L'AE non è stato ancora risolto?	Esito	Se l'AE è stato risolto indicare la data precisa di risoluzione
☐ Si ☐ No	☐ AE trattato con successo ☐ AE in corso di trattamento ☐ AE non trattato ☐ AE trattato con sequele	___-___-_____(gg-mm-aaaa)

SOMMARIO DEL VOLONTARIO	
1. Data in cui è stato firmato il consenso informato	___-___-_____ (gg-mm-aaaa)
2. Il soggetto è stato incluso nello studio? ☐ Si, per favore rispondere alle domande da 3 a 6 ☐ No, quale è stata la causa della non inclusione |_____|	
3. Il soggetto ha avuta esperienza di eventi avversi durante lo studio?	☐ Si ☐ No
4. Il soggetto ha avuto necessità di trattamenti concomitanti nel corso dello studio?	☐ Si ☐ No
5. Il soggetto ha completato lo studio? ☐ Si, data di fine studio ___-___-_____ ☐ No Se No, quale è stata la causa principale per cui il volontario si è ritirato o è stato ritirato dallo studio? Indicare una delle motivazioni riportate qui sotto ☐ Evento avverso ☐ Violazione del protocollo, specificare |_____| ☐ Ritiro del consenso informato, specificare |_____| ☐ Lost to follow-up ☐ Altro, specificare |_____|	
6. Quale è lo stato del volontario alla fine dello studio ? ☐ Screening fallito ☐ Ritirato ☐ Studio completato ☐ Lost to follow-up	

Confermo che tutte le informazioni riportate nel CRF sono accurate e complete.

_____ ___-___-_____

Firma dello Sperimentatore gg mm aaaa

15.2 Curriculum vitae

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

FORMATO EUROPEO
PER IL CURRICULUM
VITAE

PERSONAL INFORMATION

Name	DR. ENZA CESTONE
Address	Via G. Moruzzi 13/A, 27100, Pavia
Telephone	3397550872
E-mail	enza.cestone@hotmail.it
Nationality	Italian
D.O.B.	07 March 1980

EDUCATION

2005	*Medecin and Surgery Degree, achieved by Pavia' University with a score of 110/110 (July 2005),with the presentation of academic defence with the title "Mycosis fungoides in childhood: description and study of two siblings"*
2006	*Examination for qualification to the Surgeon Doctor profession'exercise, argued by Pavia's University in the 2005, second session*
2009	*Specialization in Dermatology and Venereology (23 October 2006), with the Presentation of academic defence with the title "Clinical, topographical and epidemiological aspects of mucocutaneous GCHD: a retrospective study of 76 patients" with the evaluation of 50/50, into specialization's school of "Dermatologia Venereologia" of Dermatological's clinic of Pavia's Study's University, San Matteo General Hospital (Pavia), Manager Prof. G. Borroni*

WORK ESPERIENCE

-Department's activity, day hospital, allergology,micologia, istopatology's sessions, at the Dermatological Clinic of San Matteo Hospital (from 2006 to 2009).

-Dermatological's Surgery's Activity (San Matteo Hospital from 2006 to 2009).

-Inclusion of patients with melanoma, followed in follow-up in ROL (Rete Oncologica Lombarda), and of patients with pemphigus and pemphigoid in the Register of Rare Disease(from 2006 to 2009).

-Selected to participate to the Euroderm Excellence 2009 in Rome, 18 to 22 November 2009

2011

-Dermatologist consultant with dermatological examinations and pediatrical dermatological examinations at the San Raffaele Hospital,Via Olgettina 60,Milan (from 2011 to present).
-Clinical investigator of the following clinical trial: "Evaluation of the efficacy of the washing solution" Acid Nanoclusterede Water (ANW) in the treatment of facial acne: a double blind, randomized, monocentric, placebo controlled clinical study" c/o San Raffaele Hospital, Via Olgettina 60, Milan (from 2011 to 2012)

2010

-Dermatologist consultant with dermatological examinations at the San Raffaele Hospital,Poliambulatorio Cardinal Schuster, Via Castellini 7,Milan (from 2010 to present).
-Dermatologist consultant with dermatological examinations at the San Raffaele Hospital, servizio Check-up, Via Respighi 2, Milan (from march to September 2010).
-Dermatological examination at the CDN, Via Puccini 7, Lacchiarella (MI) from 2010 to present.
-Dermatologist consultant with dermatological examination at the Nursing Home of Cervesina (pv) and Casei Gerola (Pv) from 2010 to 2012.
-Dermatologist consultant for dermocosmetic's test at Farcoderm Srl, Via Angelini 21 27028 San Martino Siccomario, Pavia and Piazzale Siena 11 Milano. Specialities: efficacy testing on cosmetic preparations, Clinical evaluation for safety and effectiveness of cosmetic products, Sun Protection Factor following COLIPA and FDA guidelines (from 2010 to present).

2009

Dermatological examinations at the LILT (Lega Italiana per la Lotta contro I Tumori, P.zza Botta 10/11 Pavia (from 2009 to present).

CONGRESS ACTIVITIES AND REFRESHERS COURSES

-XX Meeting Gised, Pavia 30 settembre-1 Ottobre 2005.
-Dermatopathology: from Pratical to Conceptual and from Conceptual to Pratical. Selected lectures in honor of Professor Albert Bernard Ackerman. Pavia, 17 Maggio 2006.
-Moxifloxacin Complicated Skin and Skin Structure Infection. Investigators' Meeting Protocol 11974. Paris 7-8 September 2006.
-IV Congresso Regionale Lombardo SIDeMAST-ADOI. Milano, 9 Marzo 2007.
-Corso di Dermatologia Estetica e Correttiva. Milano, 14-15 Settembre 2007.
-Acne: una giornata in ambulatorio. Problemi e discussioni. Milano, 13 Ottobre 2007.
-Convegno"Gestione Integrata del paziente psoriasico". Pavia, 27 Ottobre 2007.
-Corso Annuale di Dermatologia-27ª Edizione. San Donato Milanese, 16 Febbraio 2008.
-VIII Corso di Aggiornamento "Genetica ed Oncologia Dermatologica". Viareggio 10-14 Marzo 2008.
-V Congresso Regionale Lombardo SIDeMast – Adoi. Bergamo, 4 Aprile 2008.
-IV Congresso Nazionale Unificato di Dermatologia e Venereologia. Napoli, 28-31 Maggio 2008.
-I° Corso Workshop Nazionale di Dermochirurgia. Novara, 27 Febbraio 2009.
-Corso tecnico-pratico di Dermatoscopia: attualità e prospettive. Bergamo, 6 Marzo 2009.
-Dermatologia Medica e Chirurgica Estetica Pratica e Qualità della vita. Pavia, 20-21 Marzo 2009.
-Fotoprotezione, quali novità?Milano, 3 Aprile 2009.
-Dermatopathology and Beyond II III. Pavia, 17-19 Aprile 2009.
-II° Corso di Dermatologia Cosmetologia. Bari, 8-9-Maggio 2009.
-VI Congresso Regionale Lombardo SIDeMAST – Adoi. Monza, 22 Maggio 2009.
-84° Congresso Nazionale SIDeMAST. Firenze, 10-13 Giugno 2009.
-II° Master di Dermatoscopia, Brescia 12/12/2009.
-AIDNID, Roma 25-27 Marzo 2010
-II° Corso di Tricologia Internistica, Milano16-17 Aprile 2010.
-La Psoriasi a Pavia: l'Eccellenza possibile, Pavia 28 Maggio 2010.
-Onicomicosi e Terapia Fotodinamica (PDT) dei tumori cutanei non melanoma (NMSC), Genova, 19 Giugno 2010.
-Vitiligo World Congress, Milano, San Raffaele, 23-25 settembre 2010.
-Derma Day-Sharing Practices, Roma 11-12 novembre 2010
-Le fibrosi cutanee, Milano 20 Novembre 2010
-Dermatologia e Ciclosporina: indicazioni classiche e nuove prospettive terapeutiche nella pratica clinica. Pavia, 27 Novembre 2010
-First International congress on state-of-the-art PRP and growth factors in dermatology, Milano, 21-22 Gennaio 2011
-Psoriasi: sostantivo singolare, femminile, Pavia, 4-6 Marzo 2011
-11° Congresso Nazionale ADMG, Un Ponte per la Dermatologia, Reggio Calabria, 16-19 Giugno 2011
-Focus on Lupus eritematosus, Milano, 24/06/2011
-La gestione degli agenti anti-TNF nelle patologie infiammatorie croniche, Pavia 9 Settembre 2011
-Dare voce all'atopia, comunicazione e menagement clinico nella Dermatite Atopica, Certosa di Pavia, 15/10/2011
- Corso teorico-pratico interattivo- Ulcere della pelle: tra micro e macro angiopatia, Roma, 10-11 Novembre 2011
-Acne: patologia, diagnosi, terapia e aspetti psicologici, Milano 19-11-2011
-Corso "One Day" 2011 di Dermatologia Plastica Isplad, Milano 26 Novembre 2011
-4° Master di Dermatoncologia e Dermatoscopia, Brescia, 17 Dicembre 2011
-Vasculiti Sistemiche: un approccio multidisciplinare. Firenze, 30 Marzo 2012.
-Incontri dermatologici- Meeting con presentazione di casistica clinica e istopatologia, Milano, 20 Aprile 2012
-Allergie, Intolleranze alimentari e cute, Brescia, 5 Maggio 2012
-Malattie cutanee Autoimmuni e Immuno-mediate "sindromi AutoInfiammatorie e Psoriasi", Milano 19 Maggio 2012
-Stage di Pratica Clinica, Milano 14-16 Giugno 2012
-Malattie cutanee autoimmuni e immunomediate, Milano 23 Giugno 2012
-Malattie cutanee autoimmuni e immunomediate "Vasculiti e Malattie Bollose", Milano 15 Settembre 2012

-My Communication Check, Milano 16 Febbraio-2013
-Corso Teorico-pratico sul Peeling Chimici, Milano 23 Marzo 2013
-Stage di Pratica Clinica in Dermatologia, Milano16-17 Aprile 2013
-34° Maggio Pediatrico Pavese, la parola al consulente, Pavia, 11 Maggio 2013
-Viaggio nelle malattie cutanee immuno-mediate, Milano, 08 Giugno 2013
-Gestione delle lesioni pigmentate cutanee, Roma, 20-21 Giugno 2013
-Acne and Rosace Days, Milano, 27-28 Settembre 2013
-Risk Management in Dermatologia, Modena, 19 Ottobre 2013
-Psoriasi, la terapia interativa, Milano, 16 Novembre 2013
-IV° Workshop di Dermoscopia Bologna, 22-23 Novembre 2013

PROFESSIONAL INTEREST

In the years of specialization in Dermatology and Venereology I have developped a great interest for clinical's dermatology in paediatric area,with a deepening of this

PUBBLICATIONS AND SCIENTIFIC'S WORKS COMUNICATIONS

-Mycosis fungoides in childhood: description and study of two siblings.
Camilla Vassallo, Valeria Brazzelli, Enza Cestone, Michela Castello, Olga Clocca, Riccardo Giovanni Borroni, Miryam Martinetti, Giovanni Borroni. Acta Derm Venereol. 2007 ;87 (6):529-32.
-Micosi Fungoide in età pediatrica: descrizione e studio di due fratelli.
Cestone E., Vassallo C, Castello M., Schiavi C., Martinetti M., Brazzelli V.Bollettino della Società Medico Chirurgica di Pavia, Volume 118, Numero 3, Ottobre 2005
-Pustolosi subcornea di Sneddon-Wilkinson e infezione cronica da Tricophyton Rubrum.
Cestone E., Vassallo C., Castello M., Schiavi C., Brazzelli V. Bollettino della Società Medico Chirurgica di Pavia, Volume 118, Numero 3, Ottobre 2005
-Evoluzione della patologia da Trychophylon Rubrum negli ultimi 30 anni: l'esperienza pavese.
Schiavi C., Vassallo C., Cestone E., Clocca O., Mosca M., Di Silverio A. Bollettino della Società Medico Chirurgica di Pavia, Volume 118, Numero 3, Ottobre 2005
-Carcinomi Basocellulari multipli in un paziente giovane sottoposto a radioterapia.
Schiavi C, Cestone E., Castello M, Clocca O., Muzio F., Caspa M. Bollettino della Società Medico Chirurgica di Pavia, Volume 118, Numero 3, Ottobre 2005
-Aspetti clinici ed immunopatologici inusuali di un caso di dermatosi IgA lineare nell'adulto.
Legoratto S., Vassallo C., Cestone E., Ronzi G., Flandrino G., Clocca O, Borroni G. Bollettino della Società Medico Chirurgica di Pavia. Volume119, 2006.
-Sifilide nodulare con aspetti clinici ed istologici di pseudolinfoma: una rara presentazione di sifilide secondaria in paziente immunocompetente.
Legoratto S., Vassallo C, Cestone E., Riveda G., Scarabotto A., Borroni G. Bollettino della. Società Medico Chirurgica di ,Pavia Volume 120 Numero 3, 2007.
-Allogenic leg transplantation: First report by Fra Angelico (1438-1440).
Borroni G., Cestone E., Ronzi G. Cover art. Sept 2008.
-Trattamento del Sarcoma di Kaposi classico con vinblastina intralesionale: sudio in 4 pazienti. Fusi I., Vassallo C., Cestone E., Borroni G. Bollettino della Società Medico Chirurgica di Pavia, Volume 121, Numero 3, Novembre 2008.
-Valutazione clinica dell'azione Sebo-normalizzante di un Integratore alimentare (Cinarepa) in soggetti che presentano pelle del viso grassa. E. Cestone, A.Micheloiti, S. Raco, S. Forti, A. Cesarani, A. Sanna, F. Marzatico. Giornale Italiano di Dermatologia e Venereologia, Volume 146- Suppl.1-N.3-Giugno 2011
-Il trattamento topico della psoriasi lieve-moderata trattata con Calcipotriolo/Betametasone Gel: descrizione di 2 casi clinici (in stampa, novembre 2013)
E.Cestone, S.R. Mercuri

ORAL COMUNICATIONS

-Terzo congresso regionale Lombardo Sidemast Adoi, 7 aprile 2006
Micosi fungoide in età pediatrica descrizione e studio di due fratelli.
C. Vassallo, E. Cestone, M. Castello, V. Brazzelli, O. Ciocca, M. Martinetti, G. Borroni.
-Quarto congresso regionale Lombardo Sidemast Adoi, 9 marzo 2007
Terapia intralesionale con metotressato in paziente con ALCL CD30+, in precedenza sottoposto a trapianto di cellule staminali per micosi fungoide
C. Vassallo, O. Ciocca, E. Cestone, P. Gabba, M. Cespa, V. Brazzelli, G. Borroni.
-Istopatologia Dermatologica Torino, 26-27 Marzo 2009
Mucosite erosiva del cavo orale: studio di un caso. Camilla Vassallo, Enza Cestone, Giovanni Borroni
-Cheratosi solari e sarcoma di Kaposi lesione in chiazza: studio di un caso.
Camilla Vassallo, Enza Cestone, Giovanni Borroni.
-Valutazione controllata con placebo di un nuovo prodotto cosmetico nel miglioramento estetico del contorno occhi.
P.Magnani, E. Caccialanza, E. Cestone, S. Raco, F. Marzatico. 13° Congresso Internazionale di Medicina Estetica, Milano 13-15 ottobre 2011.

POSTERS

-SIDCO PERUGIA 16-19 Aprile 2008
CORRELAZIONE TRA CLINICA, DERMATOSCOPIA E ISTOLOGIA NEL MELANOMA
M.Cespa, M.Gatti, E.Cestone, L.Berardi, G.Flandrina*, M.Luciani* e G.Borroni.
-SIDCO MODENA 15-18 Aprile 2009
SOPRAVVIVENZA IN PAZIENTI AFFETTI DA MELANOMA: CASISTICA CLINICA
Marco Gatti, Maddalena Cespa, Stefania Legoratto, Enza Cestone, Michela Antonineti, Annalisa De Silvestri*.
-SIDeMaST: 85° Congresso Nazionale, Rimini 19-22 Maggio 2010
MELANOMA CUTANEO: DISCUSSIONE SULLA SOPRAVVIVENZA A 5 ANNI DALLA DIAGNOSI DI MELANOMA CON SPESSORE ≥ 1 mm
Maddalena Cespa, Giorgia Ronzi, Enza Cestone, Marco Gatti, Valeria Brazzelli, Annalisa De Silvestri*
- Le Psoriasi-Convegno Multidisciplinare, Napoli, 28-30 Novembre 2013
EFFICACIA, TOLLERABILITA' E COMPLIANCE DEL TRATTAMENTO CON CALCIPOTRIOLO/BETAMETASONE DIPROPIONATO GEL NELLA PSORIASI DI GRADO LIEVE-MODERATO
G.Ronzi, E. Cestone, S.R. Mercuri

PERSONAL INTEREST

In my free time I devote myself to the lecture,to the sport (sky,swimming-pool and running),and to the music

Enza Cestone

europass

Curriculum vitae

Personal information

First name(s) / Surname(s)	Vincenzo Nobile
Address(es)	27, Via Po, 27028, Travacò Siccomario (PV), Italy
Telephone(s)	0039 (0)382 25504 Mobile: 0039 334 2967960
E-mail	vincenzo.nobile@farcoderm.com; nobile.vincenzo@gmail.com
Nationality	Italian
Date of birth	20 February 1979
Gender	Male

Work experience

2012-present — **International Development Coordinator**

Main activities and responsibilities: Start up of new subsidiaries. Scientific customer care of foreign Customers.

Name and address of employer: Farcoderm srl - Via Mons. Angelini, 21, 27028 San Martino Siccomario (PV) - Italy

Type of business or sector: Safety and efficacy testing in the cosmetic, dietary supplement and medical device fields.

2008-2012 — **R&D Specialist**

Main activities and responsibilities: Improvement of achieved goals.

Name and address of employer: Farcoderm srl - Via Mons. Angelini, 21, 27028 San Martino Siccomario (PV) - Italy

Type of business or sector: Safety and efficacy testing in the cosmetic, dietary supplement and medical device fields.

2006-2008 — ***in vitro* and sunscreen testing manager**

Main activities and responsibilities:

- Evaluation of sunscreen products (Colipa/CTFA SA,JCIA, CTFA 2006, FDA, PPD JCIA 1995 methods; Water Resistant/Very WaterResistant Guidelines Colipa 2005, Water Resistant/Very Water Resistant FDAmethod).
- Development and validation of new *in vitro* and *in vivo* protocols.
- Development and validation of image analysis techniques as a quantitative tool in dermatological analysis (i.e. volumising effect for lips, 'push up' effect for breast and buttocks, lifting effect for eyelids, lengthening effect for eyelashes)
- Attendance to the Colipa UVAPF launch meeting in Brussels
- Evaluation of the efficacy of food supplements
- Statical analysis of clinical trial

Name and address of employer: Farcoderm srl - Via Giacomo Franchi, 4 Pavia (PV) - Italy

Type of business or sector: Safety and efficacy testing in the cosmetic, dietary supplement and medical device fields.

2005-2006 — **Technician**

Main activities and responsibilities: Instrumental Technician for dermatological analysis and validation of Colipa and FDA methods (both static and water resistant/very water resistant) for the evaluation of sunscreen products performance.

- Validation of the assessment process for the evaluation of the efficacy of sunscreen products according to Colipa and FDA methods and water resistance evaluation guidelines.
- Development of the guidelines (for correct use of machinery, maintenance, calibration control) used for calibrating dermatological analysis instruments (Courage+Khazaka GmbH) and solar simulation equipment (Solar Light Co. Inc, PA)
- Scientific reporting

Name and address of employer: Farcoderm srl - Via Giacomo Franchi, 4 Pavia (PV) - Italy

Type of business or sector: Safety and efficacy testing in the cosmetic, dietary supplement and medical device fields.

2004-2005	**Scientist**
Main activities and responsibilities	Continuation of three year degree project on the development and optimisation of an ex vivo experimental model (spinal cord slices) used to study neurodegenerative cellular mechanisms in a motorneuron disease (Amiotrophic Lateral Sclerosis, ALS). Techniques acquired: confocal microscopy; differential centrifugation (human blood, murine spinal cord, and brain); spectrophotometry; spectrofluorimetry.
Name and address of employer	Cellular and Molecular Pharmacology Laboratory (Departments: Physiological and Pharmacological, Cellular and Molecular Sciences) - Piazza Botta, 1, 27100 Pavia (Italy)
Type of business or sector	Education

Education and training

2008	**Enrolment on Biologist Register** (section A, enrolment number 059088)
1998-2005	**University of Pavia**
Title of qualification awarded	Doctor in Biological Sciences (physiopathological research)
Qualification	107/110
1993-1998	**Scientific High School "Galileo Galilei"**
Title of qualification awarded	Scientific maturity
Qualification	49/60

Personal skills and competences

Mother tongue(s): Italian

Other language(s)

Self-assessment	Understanding				Speaking				Writing	
European level (*)	Listening		Reading		Spoken interaction		Spoken production			
English	C2	Proficient	C2	Proficient	C2	Proficient	C2	Proficient	C2	Proficient

(*) *Common European Framework of Reference for Languages*

Technical skills and competences	Good knowledge of the cosmetic rules and regulation in the EU market. Good knowledge of the cosmetic trends. Good knowledge of the cosmetic testing framework.
Computer skills and competences	Excellent knowledge of: Microsoft office software (all versions), software for instrument management and data elaboration for dermatological analysis, image analysis software (ImageJ and Adobe photoshop), statistical analysis software (NCSS/PASS/GESS). Good knowledge of Visual basic programming language (VB.NET) and Microsoft SQL server. Good Knowledge of QlikView (software for business intelligence analysis).
Driving licence	Category B

Publications

Pubblications

Nobile V, Buonocore D, Michelotti A, Marzatico F. Anti-aging and filling efficacy of six types hyaluronic acid based dermo-cosmetic treatment: double blind, randomized clinical trial of efficacy and safety. Journal of Cosmetic Dermatology, 13, 277-287, 2014.

Puoci F, **Nobile V,** Zanzottera F, Piangiolino C. Potential control in calories intake and prolonged satiety effect promoted by apple polyphenols. Agro FOOD Industry Hi Tech, Vol 25(6), November/December 2014.

Cheminet H, Seroul P, **Nobile V.** Image Processing and Analysis to Evaluate the Effects of Porous Polyamide Microspheres in Cosmetics. Cosmetics & Toiletries, Vol. 128, No. 9, September 2013

Doria E., Buonocore D., Michelotti A., **Nobile V.,** Marzatico F. Evaluation of a phyto-supplement efficacy as adjuvant in reducing body weight and fat mass in overweight women. Current topics in nutraceutical research vol. 11, no. ½, pp 21-28, 2013.

Sica V, **Nobile V.** α- e γ-Benzopironi Caso clinico sugli effetti anti-edemigeni. L'integratore Nutrizionale 2013-16(2), pp. 31-22.

Buonocore D, Nobile V, Michelotti A, Marzatico F. Clinical Efficacy of a Cosmetic Treatment by Crescina® Human Follicle Stem Cell on Healthy Males with Androgenetic Alopecia. Dermatol Ther (Heidelb) (2013) 3:53–62

Buonocore D, Lazzeretti A, Tocabens P, **Nobile V,** Cestone E, Santin G, Bottone MG, Marzatico F. Resveratrol-procyanidin blend: nutraceutical and antiaging efficacy evaluated in a placebo controlled, double-blind study. Clin Cosmet Investig Dermatol. 2012;5:159-65. doi: 10.2147/CCID.S36102. Epub 2012 Oct 5.

Santoro B, Bigini P, Levandis G, **Nobile V,** Biggiogera M, Botti F, Mennini T, Curti D. Evidence for chronic mitochondrial impairment in the cervical spinal cord of a murine model of motor neuron disease. Neurobiol Dis. 2004 Nov;17(2):349-57.

Posters

Reyes E, Vitale MA, Cestone E, Michelotti A, **Nobile V.** Efficacy of a combined-treatment based on an overnight serum gel and a day gel cream SPF 50 in reducing the visibilità of skin blotches and creating a more evening complexion. CosmoDerm 2012 meeting. November 22nd-24th 2012 Madrid Spain.

Giardina S. **Nobile V**, Michelotti A., Janson J. Hydrolised hyaluronic acid shows higher biological efficacy.

Curti D., **Nobile V.**, Bigini P., Levandis G., Santoro B., Mennini T (2003). Mitochondrial dysfunction in a murine models of motor neuron disease. Libro degli abstracts del 14th international symposium on ALS/mnd, supplemento 1 (4) pag. 123 (Taylor&Francis healthsciences)

Santoro B., Levandis G., **Nobile V.**, Bendotti C., Curti D. (2004). Analysis of the early mitochondrial damage in G93A-SOD1 transgenic mice (Sod1-tg). Libro degli abstracts del 15th international symposium on ALS/mnd, supplemento 2 (5) pag. 88 (Taylor&Francis healthsciences)

Oral communications

Skin and Hair ageing: facts, figures and innovative assessment. Innovation zone In-cosmetics, Wednesday 17th April

Evaluation of the anti-wrinkle efficacy and the lifting effect of a professional cosmetic treatment. Verona June, 15th 2012

"Sun protection information day - La valutazione dell'efficacia UVB dei prodotti per la protezione solare". Garbagnate Milanese, 7 maggio 2008.

Courses

19/11.2011 - Corso di specializzazione di primo livello in adipometria svolto da Hosand Technologies s.r.l.

27/10/2009 - partecipazione al convegno "Cosmetici naturali e biologici", sede S.I.S.T.E. via Filargo 38, Milano (Italy)

29/05/2007 - partecipazione al seminario "Sun Concept Day" sugli aggiornamenti tecnologici relativi ai prodotti destinati alla protezione solare, dedicato agli operatori dell'industria cosmetica italiana. Auditorium di Federchimica, Milano

11/05/2009 - partecipazione al "Corso antincendio teorico pratico per Attività a rischio medio conforme al DM 10/03/98" Garbagnate Milanese, Milano (Italy)

20/05/2007 - partecipazione al "Colipa UVA method Launch meeting. Colipa -- Avenue Hermann-Debroux, Brussels (Belgium)

03/02/2006 - partecipazione al convegno "Le 3R incontrano la didattica: Quali alternative all'impiego dell'animale?" Palazzo Greppi - Sala Napoleonica Università degli studi di Milano, Milano (Italy)

25/05/2005 - Corso svolto da Chemtek Analytica in collaborazione con PhenomenexTM: "Come sviluppare la separazione in HPLC - Fase inversa"

10/05/2005 partecipazione al "II Meeting on the molecular mechanism of neurodegeneration" Aula Magna Università degli studi di Milano, Milano (Italy)

16/03/2005 - Corso svolto da Chemtek Analytica in collaborazione con PhenomenexTM: "L'analisi HPLC in fase inversa: lavorare nelle condizioni ottimali"

19/11-25/11-3/12-11/12-18/12/2013 - Corso di formazione intensivo sullo sviluppo di analisi di business intelligence con QlikView.

15.3 Randomization list

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

Randomization Lists

Summary		
Randomization Algorithm	Efron's Biased Coin (p = 0,67)	
Search Iterations	1	
Number of Groups	2	
Total Sample Size	110	
Group Sample Sizes	Actual	Target
-- Dermawand Active	55	55
-- Dermawand Placebo	55	55

References

Piantadosi, S. 2005. Clinical Trials - A Methodological Perspective. John Wiley & Sons. New Jersey.
Pocock, S.J. 1983. Clinical Trials - A Practical Approach. John Wiley & Sons. New York.
Rosenberger, W.F., and Lachin, J.M. 2002. Randomization in Clinical Trials - Theory and Practice. John Wiley & Sons. New York.

Randomization List

Subject ID	Group Assignment	Largest % Deviation from Target	Cumulative Sample Size (Dermawand Active, Dermawand Placebo)
1	Dermawand Active	0,9%	(1, 0)
2	Dermawand Placebo	0,0%	(1, 1)
3	Dermawand Placebo	0,9%	(1, 2)
4	Dermawand Placebo	1,8%	(1, 3)
5	Dermawand Placebo	2,7%	(1, 4)
6	Dermawand Active	1,8%	(2, 4)
7	Dermawand Active	0,9%	(3, 4)
8	Dermawand Active	0,0%	(4, 4)
9	Dermawand Active	0,9%	(5, 4)
10	Dermawand Placebo	0,0%	(5, 5)
11	Dermawand Active	0,9%	(6, 5)
12	Dermawand Placebo	0,0%	(6, 6)
13	Dermawand Placebo	0,9%	(6, 7)
14	Dermawand Active	0,0%	(7, 7)
15	Dermawand Active	0,9%	(8, 7)
16	Dermawand Active	1,8%	(9, 7)
17	Dermawand Placebo	0,9%	(9, 8)
18	Dermawand Placebo	0,0%	(9, 9)
19	Dermawand Placebo	0,9%	(9, 10)
20	Dermawand Active	0,0%	(10, 10)
21	Dermawand Active	0,9%	(11, 10)
22	Dermawand Placebo	0,0%	(11, 11)
23	Dermawand Active	0,9%	(12, 11)
24	Dermawand Placebo	0,0%	(12, 12)
25	Dermawand Placebo	0,9%	(12, 13)
26	Dermawand Placebo	1,8%	(12, 14)
27	Dermawand Active	0,9%	(13, 14)
28	Dermawand Active	0,0%	(14, 14)
29	Dermawand Active	0,9%	(15, 14)
30	Dermawand Placebo	0,0%	(15, 15)
31	Dermawand Placebo	0,9%	(15, 16)
32	Dermawand Active	0,0%	(16, 16)
33	Dermawand Placebo	0,9%	(16, 17)
34	Dermawand Active	0,0%	(17, 17)
35	Dermawand Active	0,9%	(18, 17)
36	Dermawand Active	1,8%	(19, 17)
37	Dermawand Placebo	0,9%	(19, 18)
38	Dermawand Active	1,8%	(20, 18)
39	Dermawand Placebo	0,9%	(20, 19)

This document is printed in two copies: one copy is filed by the In site Study Director at Farcoderm srl, a copy is filed by the person responsible for the study at the Sponsor site. The electronic copy of this document is filed at Farcoderm srl server. Access to this document is restricted by the policy of the local network of Farcoderm srl only the In site Study Director and server administrator. The In site Study Director will prepare a single sealed envelope containing the information on the tested product for each subject participating in the study. Envelopes will be stored in a safe, restricted access place. This document will be filed in the study file at the end of the study.

Subject ID	Group Assignment	Largest % Deviation from Target	Cumulative Sample Size (Dermawand Active, Dermawand Placebo)
40	Dermawand Placebo	0,0%	(20, 20)
41	Dermawand Active	0,9%	(21, 20)
42	Dermawand Active	1,8%	(22, 20)
43	Dermawand Placebo	0,9%	(22, 21)
44	Dermawand Active	1,8%	(23, 21)
45	Dermawand Active	2,7%	(24, 21)
46	Dermawand Active	3,6%	(25, 21)
47	Dermawand Placebo	2,7%	(25, 22)
48	Dermawand Active	3,6%	(26, 22)
49	Dermawand Placebo	2,7%	(26, 23)
50	Dermawand Placebo	1,8%	(26, 24)
51	Dermawand Active	2,7%	(27, 24)
52	Dermawand Active	3,6%	(28, 24)
53	Dermawand Active	4,5%	(29, 24)
54	Dermawand Active	5,5%	(30, 24)
55	Dermawand Placebo	4,5%	(30, 25)
56	Dermawand Active	5,5%	(31, 25)
57	Dermawand Active	6,4%	(32, 25)
58	Dermawand Active	7,3%	(33, 25)
59	Dermawand Placebo	6,4%	(33, 26)
60	Dermawand Active	7,3%	(34, 26)
61	Dermawand Active	8,2%	(35, 26)
62	Dermawand Placebo	7,3%	(35, 27)
63	Dermawand Placebo	6,4%	(35, 28)
64	Dermawand Placebo	5,5%	(35, 29)
65	Dermawand Placebo	4,5%	(35, 30)
66	Dermawand Placebo	3,6%	(35, 31)
67	Dermawand Placebo	2,7%	(35, 32)
68	Dermawand Active	3,6%	(36, 32)
69	Dermawand Active	4,5%	(37, 32)
70	Dermawand Placebo	3,6%	(37, 33)
71	Dermawand Active	4,5%	(38, 33)
72	Dermawand Active	5,5%	(39, 33)
73	Dermawand Placebo	4,5%	(39, 34)
74	Dermawand Placebo	3,6%	(39, 35)
75	Dermawand Active	4,5%	(40, 35)
76	Dermawand Active	5,5%	(41, 35)
77	Dermawand Placebo	4,5%	(41, 36)
78	Dermawand Placebo	3,6%	(41, 37)
79	Dermawand Active	4,5%	(42, 37)
80	Dermawand Placebo	3,6%	(42, 38)
81	Dermawand Placebo	2,7%	(42, 39)
82	Dermawand Placebo	1,8%	(42, 40)
83	Dermawand Placebo	0,9%	(42, 41)
84	Dermawand Active	1,8%	(43, 41)
85	Dermawand Placebo	0,9%	(43, 42)
86	Dermawand Placebo	0,0%	(43, 43)
87	Dermawand Placebo	0,9%	(43, 44)
88	Dermawand Active	0,0%	(44, 44)
89	Dermawand Placebo	0,9%	(44, 45)
90	Dermawand Placebo	1,8%	(44, 46)
91	Dermawand Active	0,9%	(45, 46)
92	Dermawand Active	0,0%	(46, 46)
93	Dermawand Placebo	0,9%	(46, 47)
94	Dermawand Active	0,0%	(47, 47)
95	Dermawand Placebo	0,9%	(47, 48)
96	Dermawand Active	0,0%	(48, 48)
97	Dermawand Active	0,9%	(49, 48)
98	Dermawand Placebo	0,0%	(49, 49)

This document is printed in two copies: one copy is filed by the in site Study Director at Farcoderm srl, a copy is filed by the person responsible for the study at the Sponsor site. The electronic copy of this document is filed at Farcoderm srl server. Access to this document is restricted by the policy of the local network of Farcoderm srl only the in site Study Director and server administrator. The in site Study Director will prepare a single sealed envelope containing the information on the tested product for each subject participating in the study. Envelopes will be stored in a safe, restricted access place. This document will be filed in the study file at the end of the study.

Subject ID	Group Assignment	Largest % Deviation from Target	Cumulative Sample Size (Dermawand Active, Dermawand Placebo)
99	Dermawand Placebo	0,9%	(49, 50)
100	Dermawand Placebo	1,8%	(49, 51)
101	Dermawand Active	0,9%	(50, 51)
102	Dermawand Active	0,0%	(51, 51)
103	Dermawand Active	0,9%	(52, 51)
104	Dermawand Placebo	0,0%	(52, 52)
105	Dermawand Placebo	0,9%	(52, 53)
106	Dermawand Active	0,0%	(53, 53)
107	Dermawand Active	0,9%	(54, 53)
108	Dermawand Active	1,8%	(55, 53)
109	Dermawand Placebo	0,9%	(55, 54)
110	Dermawand Placebo	0,0%	(55, 55)

This document is printed in two copies: one copy is filed by the in site Study Director at Farcoderm srl, a copy is filed by the person responsible for the study at the Sponsor site. The electronic copy of this document is filed at Farcoderm srl server. Access to this document is restricted by the policy of the local network of Farcoderm srl only the in site Study Director and server administrator. The in site Study Director will prepare a single sealed envelope containing the information on the tested product for each subject participating in the study. Envelopes will be stored in a safe, restricted access place. This document will be filed in the study file at the end of the study.

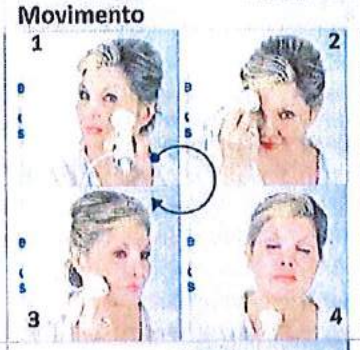
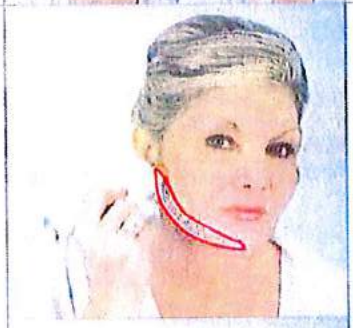
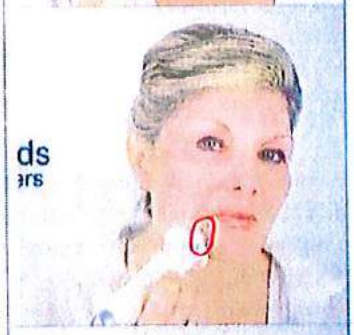
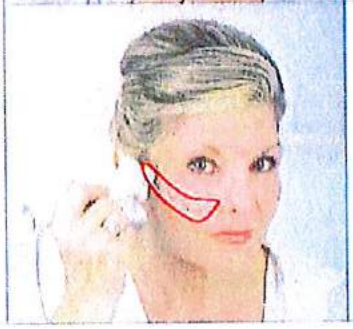
15.4 Way of use

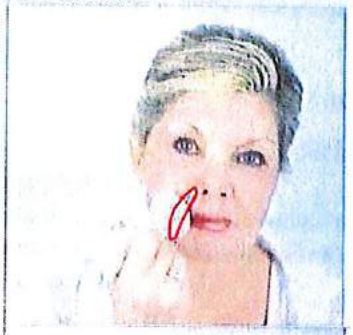
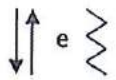
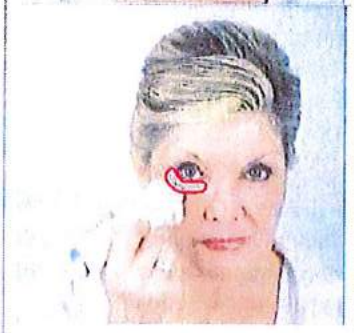
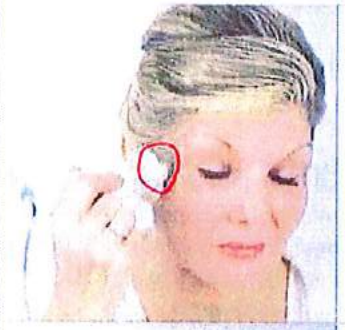
Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

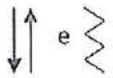
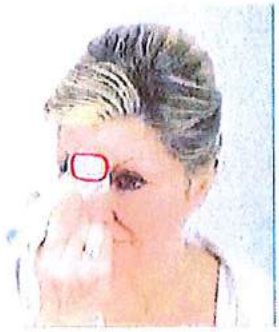
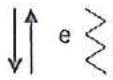
⓪ PRIMA DI UTILIZZARE DERMAWAND

① Pulisci la pelle del viso con il tuo normale detergente
② Asciuga tamponando
③ Applica il prodotto CREMA A (DermaVitál® Pre-Face Treatment)

PRIMO PASSAGGIO

	Movimento		Potenza e tempo
① Viso e collo		Grandi movimenti circolari o lineari a seconda dell'area.	✷ Max: 7-9 ◷ 90 secondi su tutto il viso
② Mandibolare		Piccoli e ravvicinati movimenti circolari della dimensione di una monetina andando avanti ed indietro per l'intera area	✷ Max: 7-9 ◷ 30-45 secondi su ciascun lato del viso
③ Rughe melolabiali (angolo della bocca)		Ravvicinati in su è in giù fino alla zona appena sopra l'osso mascellare. Risalire con lo stesso movimento. Se ti è più comodo proseguire con movimento a zig-zag.	✷ Max: 7-9 ◷ 30 secondi a destra e 30 secondi a sinistra
④ Guance (sotto lo zigomo)		Movimenti circolari ravvicinati muovendoti verso l'attaccatura dei capelli (in prossimità dell'orecchio).	✷ Max: 7-9 ◷ 30 secondi a destra e 30 secondi a sinistra

	Movimento		Potenza e tempo
⑤ **Rughe naso labiali**		Movimenti ravvicinati a zig-zag seguendo il profilo della ruga. Risalire con lo stesso movimento.  È possibile notare un alone da rosa a rosso accompagnato da una sensazione di calore	✳ Max: 7-9 🕓 30-45 secondi a destra e 30-45 secondi a sinistra
⑥ **Rughe periorbitarie (sotto gli occhi)**		Partendo dall'angolo interno dell'occhio, con un unico movimento, muoviti verso l'angolo esterno. Utilizzare il più vicino possibile alla attaccatura delle ciglia in modo da sentirsi a proprio agio. È possibile applicare CREMA B (ma senza lasciare il viso bagnato)	✳ Media: 4-6 🕓 30-45 secondi a destra e 30-45 secondi a sinistra Non utilizzare Dermawand® alla massima potenza
⑦ **Rughe perioculari del canto esterno (rughe a "zampa di gallina")**		Movimenti circolari ravvicinati 	✳ Max: 7-9 🕓 30-45 secondi a destra e 30-45 secondi a sinistra
⑧ **Area palpebrale**		Tirare la cute verso l'alto partendo dalla zona centrale delle sopraciglia. Ripetere lo stesso esercizio sulla zona laterale esterna ed interna.  Fino al terzo giorno sarà possibile notare un arrossamento	✳ Media-Max: 5-8 🕓 20 secondi per ciascun punto. Ripetere due volte l'esercizio sullo stesso occhio

	Movimento		Potenza e tempo
⑨ Fronte		Tirare la cute della fronte verso l'alto fino all'attaccatura dei capelli con un lieve movimento a zig-zag. Arrivati all'attaccatura dei capelli tieni la pelle tesa per 15 secondi. I punti da trattare sono: angolo esterno, centrale ed interno del sopracciglio. 	❋ Max: 7-9 ◷ 45 secondi
⑩ Rughe glabellari (in mezzo alle sopracciglia)		Movimenti a zig-zag dal basso verso l'alto. 	❋ Max: 7-9 ◷ 45 secondi

	SECONDO PASSAGGIO
①	Assicurati che il tuo DermaWand sia al più alto livello possibile in termini di comfort.
②	Applica il prodotto idratante (CREMA B) su tutto il viso
③	Quando sei pronto a partire sulla cute del collo parti dalla linea centrale del collo e facendo movimenti lineari dal basso verso l'alto lavora entrambi I lati. Questa fase dura circa 1 minuto.
④	Successivamente passa alla mandibola e con lunghi movimenti a zig-zag o larghi movimenti circolari spostati verso l'orecchio. Continua così per circa 30 secondi su ogni lato del viso per un totale di 1 minuto.
⑤	Quindi continua sulle rughe nasolabiali, ricordando di eseguire il trattamento anche sulla guancia e sotto agli occhi. Esegui movimenti a zig-zag o movimenti circolari su tutta la zona per circa 30 secondi per lato, per un totale di un minuto.
⑥	Utilizza il DermaWand sulla fronte e, infine, spostati in basso, su entrambi i lati, sulla cute che presentano le zampe di gallina. In queste aree esegua grandi movimenti circolari e a zig-zag per un totale di 1 minuto.
⑦	Riapplica il prodotto idratante (Crema B) ed hai finito.

Visita: http://www.youtube.com/watch?v=Uj2mcSMDKxg

15.5 Cosmetic products formula

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

INCI Ingredients List for Kolmar Laboratories Formula of DermaVital® Pre-Face Treatment

Water (Aqua)

Propanediol

Beta-Glucan

Glycerin

Chamomilla Recutita (Matricaria) Flower Extract

Aloe Barbadensis Leaf Juice

Camellia Oleifera Leaf Extract

Picea Abies Extract

Carbomer

Allantoin

Glycereth-18 Ethylhexanoate

Polyquaternium-71

Potassium Sorbate

Benzoic Acid

Phenoxyethanol

Glycereth-18

Disodium EDTA

Dehydroacetic Acid

Citric Acid

Sodium Hydroxide

Yellow 6 (C.I. 15985)

INCI Ingredients List for Polysciences Formula of DermaVital Skin Quench® Moisturizer

Water (Aqua)

Hydrogentaed Ethyl Hexyl Olivate

Cetearyl Alcohol

Glycerin

Propanediol

Arachidyl Alcohol

Cety Alcohol

Isocetyl Salicylate

Bidens Pilosa Extract

Blaeis Guineensis (Palm) Oil

Tamarindus Indica Seed Extract

Helianthus Annuus (Sunflower) Seed Oil

Chamomilla Recutita (Matricaria) Flower Extract

Glycirrhiza Glabra (Licorice) Root Extract Sodium PCA

Camellia Sinensis Leaf Extract

Cetearyl Glucoside

Pentylene Glycol

Aloe Barbadensis Leaf Extract

Coleus Forskohlii Root Extract

Behenyl Alcohol

Olea Europaea (Olive) Fruit Extract

Glyceryl Caprylate

Isopropyl Jojobate

Sodium Hyaluronate

Algae Extract

Tocopherol

Tocopheryl Acetate

Allantoin

Pullulan

Jojoba Alcohol

Triticum Vulgare (Wheat) Germ Extract

Saponaria Officinalis Extract

Polygonum Cuspidatum (Japenses Bamboo) Extract

Gossypium Herbaceum (Cotton) Seed Oil

Squalane

Jojoba Esters

Mangifera Indica (Mango) Seed Butter

Prunica Granatum Extract

Dimethicone/ Vinyl Dimethilcone Crosspolymer

Ascorbyl Palmitate

Chrithmum Maritimum Extract

Linum Usitatissimum (Linseed) Oil

Euphrasia Officialis Extract

Hydrogenated Olive Oil Unsaponifiables

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer

Carbomer

Sorbitan Olivate

Dimethicone

Arachidyl Glucoside

Polymethylmethyl

Acrylates/ C10-30 Alkyl Acrylate Crosspolymer

Sodium Phytate

Cyclopentasiloxane

Xanthan Gum

Potassium Sorbate

Arginine

Polysorbate 60

Caprae Lac (Goat Milk)

Citric Acid

Phenoxyethanol

Ethylene Brassylate

Benzoic Acid

Dehydroacetic Acid

15.6 Site initiation checklist

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com

SITE INITIATION CHECKLIST

Study name:	Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®)
Study code:	FU.04.C.I. 2013/GCP01
Sponsor/investigator:	Enza Cestone
Name of study site:	Farcoderm s.r.l. - Via Mons. Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Date of initiation visit:	03/02/2014

Before the clinical phase of the trial commences, the quality of the site was verified by the Sponsor study monitor through:

☒ On-Site initiation visit
☐ Site initiation phone call
☐ Site initiation teleconference

The items listed in this checklist were discussed with the *in site* study monitor. By signing "Site initiation checklist" the study monitor ensures that the site quality is appropriate and the clinical phase of the study can be started.

1. Key study contact

Name	Contact information
Vincenzo Nobile	Tel: 0039 (0)382 25604
	e-mail: vincenzo.nobile@farcoderm.com

2. Study personnel in attendance

Name	Position in the study
Enza Cestone	Principal Investigator, MD (Dermatologist)
Marta Pisati	Co-investigator, Dr (Biologist)
Cristina Scillroni	Assistant, Dr (Biologist)
Vincenzo Nobile	in site study monitor, Dr (Biologist)

3. Approved study documents

Approved study documents	Yes	No	NA	Version and date
3.1. Study protocol	☒	☐	☐	3 17.01.2014
3.2. Informed consent form	☒	☐	☐	3 28.01.2014
3.3. Subject information sheet	☒	☐	☐	0 31.01.2014
3.4. Advertisement for subject recruitment	☐	☐	☒	
3.5. Study specific documents				
3.4.1. DermaWand user guide	☒	☐	☐	1 03.02.2014
3.4.2. CCCS user guide	☒	☐	☐	

4. Reviewed protocol with investigator and key study personnel

Item	Discussed? Yes	No	NA
4.1. Purpose of the study	☒	☐	☐
4.2. Inclusion/Not-inclusion criteria	☒	☐	☐
4.3. Way of use of the investigational product	☒	☐	☐
4.4. Specimen collection, storage and processing procedures	☐	☐	☒
4.5. Required clinical information needed for study	☐	☐	☒
4.6. Performance evaluation and interpretation of results	☒	☐	☐
4.7. Data collection and completion of case report forms	☒	☐	☐
4.8. Documenting protocol violations (deviations from the protocol)	☒	☐	☐

Notes
None.

	SITE INITIATION CHECKLIST	2(3)
Study name:	Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®)	
Study code:	FU.04.C.I._2013/GCP01	
Sponsor/investigator:	Enza Cestone	
Name of study site:	Farcoderm s.r.l. - Via Mons. Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy	
Date of initiation visit:	03/02/2014	

5. Conducted qualification site visit (personnel and facilities)

Item	Yes	No	NA
5.1. A key study contact has been identified	☒	☐	☐
5.2. Investigator has sufficient qualification to conduct the study	☒	☐	☐
5.3. Other personnel will be participating in the study (see delegation log)	☒	☐	☐
5.4. Facilities appear adequate for the study (space, equipment, etc.)	☒	☐	☐
5.5. Storage for participant and study files is adequate and secure	☒	☐	☐
5.6. Adequate written standard operating procedures are available	☒	☐	☐
5.7. Secure storage of specimens is available	☐	☐	☒
5.8. Secure storage of source documents is available	☒	☐	☐

6. Study management and record-keeping requirements

	Discussed?		
Item	Yes	No	NA
6.1. Obligations of investigator and key study personnel			
6.1.1. Conduct study according to written protocol	☒	☐	☐
6.1.2. Document all unanticipated events	☒	☐	☐
6.1.3. Accurately report all data and observations	☒	☐	☐
6.1.4. Observe GCP	☒	☐	☐
6.2. Human subject safety and confidentiality			
6.2.1. Conduct informed consent process according IRB approved form	☒	☐	☐
6.2.2. Participant identifiers will be properly masked	☒	☐	☐
6.2.3. Participant specimens will be coded per protocol requirements	☐	☐	☒
6.2.4. Storage of participant records secure, protects their confidentiality	☒	☐	☐
6.3. Reporting of study results			
6.3.1. A study report will be drafted and approved by the PI	☒	☐	☐
6.3.2. Stipulations for scientific publications	☒	☐	☐
6.3.3. Stipulations for presentations at professional meetings	☐	☐	☒

7. Study management and record-keeping requirements

	Discussed?		
Item	Yes	No	NA
7.1. Data collection, verification and transmission procedures			
7.1.1. Timely completion of case report forms (CRF)	☒	☐	☐
7.1.2. CRF review and verification for accuracy	☒	☐	☐
7.2. Contents of investigator's study file	Yes	No	NA
7.2.1. Current protocol version	☒	☐	☐
7.2.2. Current subjects information sheet and informed consent form	☒	☐	☐
7.2.3. Any other written information provided to patients	☒	☐	☐
7.2.4. Independent Ethical Committee approval	☒	☐	☐
7.2.5. Statement of investigator	☒	☐	☐
7.2.6. Insurance statement	☒	☐	☐
7.2.7. Unblinding procedure for blinded trials	☒	☐	☐
7.2.8. Consent and subject status log	☒	☐	☐
7.2.9. Adverse event log	☒	☐	☐
7.2.10. Signature and delegation log	☒	☐	☐
7.2.11. Monitoring log	☒	☐	☐
7.2.12. Sample copy of CRF	☒	☐	☐
7.3. Investigational product inventory requirements			
7.3.1. Receipt log of all investigational products	☒	☐	☐
7.3.2. Verification of investigational product accountability	☒	☐	☐
7.4. Record retention and accessibility			
7.4.1. Administrative and subject records maintained for at least ten years	☒	☐	☐

SITE INITIATION CHECKLIST

Study name:	Clinical-instrumental assessment of the efficacy of an aesthetic device (DermaWand®)
Study code:	FU.04.C.I. 2013/GCP01
Sponsor/Investigator:	Enza Cestone
Name of study site:	Farcoderm s.r.l. - Via Mons. Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Date of initiation visit:	03/02/2014

8. Adverse event/device malfunction reporting requirements

Item	Discussed? Yes	No	NA
8.1. Contact Monitor/Investigator to report AE or SAE (Sponsor to PI)	☒	☐	☐
8.2. Contact Sponsor to report AE or SAE (PI to Sponsor)	☒	☐	☐

9. Others Monitor observations

None.

10. Discuss significant concerns

- The way of compliance to product use will be checked
- DermaWand® way of use

11. Summary and conclusion

Kelly Willet
Monitor's Name (print)

Signature

FEB 3 2014
Date

Vincenzo Nobile
In site study monitor

Signature

FEB 3 2014
Date

15.7 Individual response data

Farcoderm srl
Head Office address: Via Angelini, 21 - 27028 San Martino Siccomario (PV) - Italy
Legal Office: Piazzale Siena 11 - 20146 (MI) - Italy - VAT n. 03893350961
Tel. +39-0382 25504 - Fax +39-0382 536006 - Mail: information@farcoderm.com - www.farcoderm.com
Company with UNI EN ISO 9001:2008 quality management system certified by Certiquality S.r.l.

no.	Vol. ID	T0	T30	VARIATION VS. T0	T30
01	M0701A	210,5	169,5		-19,5%
02	S0379S	329,8	292,6		-11,3%
03	B0012G	421,5	435,0		3,2%
04	B0023B	301,7	293,4		-2,8%
05	G0135S	428,0	368,8		-13,8%
06	B1495M	330,0	245,9		-25,5%
07	P1529I	265,8	239,8		-9,8%
08	C0085N	285,6	321,3		12,5%
09	P0281E	332,5	259,7		-21,9%
10	N0270P	315,1	265,2		-15,8%
11	G1972E	209,9	166,3		-20,8%
12	Z0618R	321,2	302,2		-5,9%
13	B1288C	286,4	212,1		-25,9%
14	P0282G	228,1	185,9		-18,5%
15	S0359L	187,0	210,3		12,5%
16	L2072M	228,3	223,1		-2,3%
17	P1979M	320,5	291,0		-9,2%
18	V2169I	334,3	213,0		-36,3%
19	A2356L	435,6	362,9		-16,7%
20	C1620T	213,0	178,0		-16,4%
21	A2360R	248,4	236,0		-5,0%
22	G2361S	305,7	280,1		-8,4%
23	M1266R	341,8	395,5		15,7%
24	M0760V	301,5	280,3		-7,0%
25	R2400C	285,6	250,7		-12,2%
26	C2404L	302,1	232,2		-23,1%
27	Z2405A	321,3	294,6		-8,3%
28	P1632E	252,6	261,5		3,5%
29	S0872M	302,5	284,1		-6,1%
30	B1081G	356,5	265,3		-25,6%
31	B2320D	315,8	294,9		-6,6%
32	G2456A	302,7	256,7		-15,2%
33	G2455M	352,1	233,3		-33,7%
34	G2454L	284,6	256,3		-9,9%
35	S2140I	253,1	275,8		9,0%
36	L1086A	228,0	252,7		10,8%
37	E1765A	365,2	340,0		-6,9%
38	M1965C	405,2	357,6		-11,7%
39	F2579C	325,6	356,1		9,4%
40	G0824G	305,5	275,5		-9,8%
41	C1963A	407,8	352,8		-13,5%
42	S0869S	356,3	303,8		-14,7%
43	F2585I	401,8	321,1		-20,1%
	Mean	309,5	276,6		-10,1%
	SEM	9,5	9,2	min	-36,3%
	t test vs. T0	---	0,0000	max	15,7%

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director

Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	S0354C	245,3	256,1		4,4%
02	G0587G	233,7	248,1		6,2%
03	B0014L	306,8	305,1		-0,6%
04	F0121F	316,4	303,7		-4,0%
05	I0170M	458,8	410,7		-10,5%
06	M0198G	258,9	263,8		1,9%
07	C0066R	287,2	310,9		8,3%
08	B0015R	365,8	352,1		-3,7%
09	R0329O	405,5	375,5		-7,4%
10	P0285R	213,7	212,8		-0,4%
11	D1967P	168,9	157,0		-7,0%
12	L1634C	241,6	307,3		27,2%
13	P0845G	222,2	232,2		4,5%
14	N0258B	215,6	206,3		-4,3%
15	F2070C	147,9	165,2		11,7%
16	B0990C	162,8	177,5		9,0%
17	O1785E	336,8	316,4		-6,1%
18	V2280A	405,6	411,8		1,5%
19	G2358M	257,1	231,0	VARIATION VS. T0	-10,2%
20	S2362L	124,5	140,5		12,9%
21	R2586L	362,8	389,3		7,3%
22	F2587P	302,7	315,1		4,1%
23	M2589S	280,1	268,2		-4,2%
24	R1440V	308,9	355,9		15,2%
25	I2598C	326,7	330,1		1,0%
26	C2620D	388,4	361,2		-7,0%
27	I2621A	412,6	385,2		-6,6%
28	G2624I	361,3	405,5		12,2%
29	F2629N	289,4	345,7		19,5%
30	S2630L	323,7	302,8		-6,5%
31	B2635A	225,8	235,3		4,2%
32	A2654G	306,7	322,8		5,2%
33	D1077A	297,4	278,5		-6,4%
34	P1606D	315,5	351,1		11,3%
35	S2652A	405,7	389,4		-4,0%
36	G2367T	289,2	325,7		12,6%
37	G2613M	345,5	330,1		-4,5%
38	G2615B	409,2	466,9		14,1%
39	R2674L	388,4	374,1		-3,7%
40	R2660R	296,7	323,6		9,1%
41	A2642S	408,2	372,2		-8,8%
	Mean	302,9	307,6		2,4%
	SEM	12,6	12,0	min	-10,5%
	t test vs. T0	--	0,2764	max	27,2%

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	M0701A	771,1	757,4		-1,8%
02	S0379S	734,8	734,3		-0,1%
03	B0012G	372,3	361,6		-2,9%
04	B0023B	295,7	229,7		-22,3%
05	G0135S	495,0	478,2		-3,4%
06	B1495M	386,8	367,5		-5,0%
07	P1529I	569,7	502,3		-11,8%
08	C0085N	549,6	567,6		3,3%
09	P0281E	347,3	280,1		-19,3%
10	N0270P	307,4	314,5		2,3%
11	G1972E	483,5	436,2		-9,8%
12	Z0618R	514,5	508,5		-1,2%
13	B1288C	293,8	259,7		-11,6%
14	P0282G	557,6	545,9		-2,1%
15	S0359L	377,1	321,0		-14,9%
16	L2072M	369,2	376,8		2,1%
17	P1979M	408,8	386,8		-5,4%
18	V2169I	485,5	305,5		-37,1%
19	A2356L	304,0	268,0		-11,8%
20	C1620T	418,0	531,0	VARIATION VS. T0	27,0%
21	A2360R	440,3	438,7		-0,4%
22	G2361S	322,7	287,2		-11,0%
23	M1266R	584,0	457,7		-21,6%
24	M0760V	602,8	584,6		-3,0%
25	R2400C	784,5	755,5		-3,7%
26	C2404L	605,2	615,1		1,6%
27	Z2405A	402,4	477,0		18,5%
28	P1632E	384,3	371,3		-3,4%
29	S0872M	705,6	711,2		0,8%
30	B1081G	498,1	405,5		-18,6%
31	B2320D	503,7	515,7		2,4%
32	G2456A	684,2	584,2		-14,6%
33	G2455M	585,5	575,5		-1,7%
34	G2454L	659,3	628,1		-4,7%
35	S2140I	702,7	584,3		-16,8%
36	L1086A	692,1	702,2		1,5%
37	E1765A	671,2	578,3		-13,8%
38	M1965C	496,6	494,0		-0,5%
39	F2579C	715,0	658,3		-7,9%
40	G0824G	685,6	702,2		2,4%
41	C1963A	706,5	711,3		0,7%
42	S0869S	542,8	502,1		-7,5%
43	F2585I	394,3	355,6		-9,8%
	Mean	521,2	493,7		-5,5%
	SEM	22,3	23,0	min	-37,1%
	t test vs. T0	---	0,0010	max	27,0%

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director

Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	S0354C	663,4	658,5		-0,7%
02	G0587G	349,7	290,6		-16,9%
03	B0014L	386,5	402,3		4,1%
04	F0121F	876,6	834,5		-4,8%
05	I0170M	734,2	678,0		-7,7%
06	M0198G	568,5	578,9		1,8%
07	C0066R	534,8	628,0		17,4%
08	B0015R	636,7	598,5		-6,0%
09	R0329O	508,5	522,9		2,8%
10	P0285R	588,0	581,6		-1,1%
11	D1967P	615,5	673,7		9,5%
12	L1634C	505,0	440,4		-12,8%
13	P0845G	235,5	253,3		7,6%
14	N0258B	448,9	336,8		-25,0%
15	F2070C	574,4	555,0		-3,4%
16	B0990C	334,4	357,5		6,9%
17	O1785E	459,0	482,4		5,1%
18	V2280A	308,9	304,0		-1,6%
19	G2358M	478,7	490,3		2,4%
20	S2362L	462,9	454,6		-1,8%
21	R2586L	721,2	756,5		4,9%
22	F2587P	305,8	301,2		-1,5%
23	M2589S	463,7	458,5		-1,1%
24	R1440V	584,1	498,1		-14,7%
25	I2598C	602,1	625,3		3,9%
26	C2620D	653,6	692,8		6,0%
27	I2621A	486,9	501,2		2,9%
28	G2624I	581,2	573,3		-1,4%
29	F2629N	405,5	468,9		15,6%
30	S2630L	708,3	702,1		-0,9%
31	B2635A	585,6	602,5		2,9%
32	A2654G	586,4	525,3		-10,4%
33	D1077A	384,1	362,2		-5,7%
34	P1606D	447,5	450,2		0,6%
35	S2652A	601,8	611,1		1,5%
36	G2367T	448,9	459,3		2,3%
37	G2613M	536,8	521,1		-2,9%
38	G2615B	605,4	598,5		-1,1%
39	R2674L	584,1	651,3		11,5%
40	R2660R	652,7	671,1		2,8%
41	A2642S	553,9	481,2		-13,1%
	Mean	531,0	527,6		-0,5%
	SEM	20,5	21,1	min	-25,0%
	t test vs. T0	---	0,6167	max	17,4%

VARIATION VS. T0

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	M0701A	395,5	397,5		0,5%
02	S0379S	231,6	230,0		-0,7%
03	B0012G	403,3	382,2		-5,2%
04	B0023B	366,7	379,9		3,6%
05	G0135S	309,5	314,2		1,5%
06	B1495M	262,5	236,9		-9,8%
07	P1529I	125,7	109,5		-12,9%
08	C0085N	140,0	130,6		-6,7%
09	P0281E	151,5	112,5		-25,7%
10	N0270P	206,6	175,5		-15,1%
11	G1972E	208,8	197,7		-5,3%
12	Z0618R	200,5	147,5		-26,4%
13	B1288C	208,6	184,0		-11,8%
14	P0282G	240,1	227,3		-5,3%
15	S0359L	138,4	141,4		2,2%
16	L2072M	205,5	184,1		-10,4%
17	P1979M	184,3	192,3		4,3%
18	V2169I	252,5	220,2		-12,8%
19	A2356L	247,2	207,5		-16,1%
20	C1620T	235,1	214,5		-8,8%
21	A2360R	168,0	170,6		1,5%
22	G2361S	215,3	225,9		4,9%
23	M1266R	284,4	236,1		-17,0%
24	M0760V	209,5	184,6		-11,9%
25	R2400C	302,6	284,1		-6,1%
26	C2404L	205,8	211,3		2,7%
27	Z2405A	324,0	293,8		-9,3%
28	P1632E	196,8	226,7		15,2%
29	S0872M	226,3	202,3		-10,6%
30	B1081G	275,5	280,1		1,7%
31	B2320D	221,9	215,2		-3,0%
32	G2456A	184,6	165,6		-10,3%
33	G2455M	385,3	328,3		-14,8%
34	G2454L	252,3	250,1		-0,9%
35	S2140I	221,1	202,3		-8,5%
36	L1086A	212,3	191,1		-10,0%
37	E1765A	232,7	212,3		-8,8%
38	M1965C	245,5	211,8		-13,7%
39	F2579C	254,6	248,5		-2,4%
40	G0824G	280,2	265,3		-5,3%
41	C1963A	251,6	255,7		1,6%
42	S0869S	203,6	178,1		-12,5%
43	F2585I	305,1	306,3		0,4%
	Mean	241,2	226,3		-6,5%
	SEM	10,0	10,2	min	-26,4%
	t test vs. T0	---	0,0000	max	15,2%

VARIATION VS. T0

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	S0354C	205,3	211,8		3,2%
02	G0587G	151,0	139,1		-7,9%
03	B0014L	341,2	345,6		1,3%
04	F0121F	214,0	223,7		4,5%
05	I0170M	193,6	193,8		0,1%
06	M0198G	405,3	411,8		1,6%
07	C0066R	359,4	342,1		-4,8%
08	B0015R	225,6	236,1		4,7%
09	R0329O	238,5	242,3		1,6%
10	P0285R	130,8	121,2		-7,3%
11	D1967P	192,8	197,4		2,4%
12	L1634C	197,5	202,5		2,5%
13	P0845G	176,7	191,3		8,3%
14	N0258B	187,9	186,7		-0,6%
15	F2070C	174,0	169,9		-2,4%
16	B0990C	304,3	279,0		-8,3%
17	O1785E	197,2	174,8		-11,4%
18	V2280A	269,5	277,3	VARIATION VS. T0	2,9%
19	G2358M	306,1	276,9		-9,5%
20	S2362L	454,0	452,8		-0,3%
21	R2586L	205,5	223,3		8,7%
22	F2587P	302,1	321,2		6,3%
23	M2589S	201,6	205,5		1,9%
24	R1440V	245,3	253,6		3,4%
25	I2598C	208,8	198,5		-4,9%
26	C2620D	284,4	262,3		-7,8%
27	I2621A	305,2	323,7		6,1%
28	G2624I	285,5	302,2		5,8%
29	F2629N	176,8	168,1		-4,9%
30	S2630L	255,4	241,3		-5,5%
31	B2635A	202,9	225,2		11,0%
32	A2654G	184,7	181,8		-1,6%
33	D1077A	205,2	184,3		-10,2%
34	P1606D	196,6	202,7		3,1%
35	S2652A	185,2	191,1		3,2%
36	G2367T	211,3	225,3		6,6%
37	G2613M	284,3	290,2		2,1%
38	G2615B	238,5	271,5		13,8%
39	R2674L	168,5	172,2		2,2%
40	R2660R	248,9	275,3		10,6%
41	A2642S	339,1	348,1		2,7%
	Mean	240,5	242,5		0,8%
	SEM	10,9	11,1	min	-11,4%
	t test vs. T0	---	0,3765	max	13,8%

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	M0701A	0,7162	0,6327		-11,7%
02	S0379S	0,4736	0,4872		2,9%
03	B0012G	0,5136	0,5197		1,2%
04	B0023B	0,7314	0,7220		-1,3%
05	G0135S	0,7126	0,6344		-11,0%
06	B1495M	0,6678	0,5835		-12,6%
07	P1529I	0,4742	0,3946		-16,8%
08	C0085N	0,5682	0,5274		-7,2%
09	P0281E	0,4244	0,3599		-15,2%
10	N0270P	0,5328	0,3835		-28,0%
11	G1972E	0,4902	0,4452		-9,2%
12	Z0618R	0,4504	0,4285		-4,9%
13	B1288C	0,4276	0,4226		-1,2%
14	P0282G	0,4592	0,3429		-25,3%
15	S0359L	0,6290	0,5309		-15,6%
16	L2072M	0,5660	0,5304		-6,3%
17	P1979M	0,7780	0,7132		-8,3%
18	V2169I	0,9328	0,8806		-5,6%
19	A2356L	0,7922	0,7915	VARIATION VS. T0	-0,1%
20	C1620T	0,7074	0,6639		-6,1%
21	A2360R	0,6554	0,6277		-4,2%
22	G2361S	0,4948	0,4467		-9,7%
23	M1266R	0,4052	0,4105		1,3%
24	M0760V	0,5145	0,3935		-23,5%
25	R2400C	0,4852	0,3602		-25,8%
26	C2404L	0,5236	0,4525		-13,6%
27	Z2405A	0,6456	0,6036		-6,5%
28	P1632E	0,5150	0,4750		-7,8%
29	S0872M	0,5253	0,5502		4,7%
30	B1081G	0,4985	0,4626		-7,2%
31	B2320D	0,4866	0,4288		-11,9%
32	G2456A	0,5523	0,4513		-18,3%
33	G2455M	0,4501	0,4302		-4,4%
34	G2454L	0,5563	0,5036		-9,5%
35	S2140I	0,6036	0,5193		-14,0%
36	L1086A	0,4856	0,4236		-12,8%
37	E1765A	0,5253	0,5036		-4,1%
38	M1965C	0,6030	0,5862		-2,8%
39	F2579C	0,7023	0,6027		-14,2%
40	G0824G	0,5985	0,5845		-2,3%
41	C1963A	0,4658	0,4233		-9,1%
42	S0869S	0,5023	0,4532		-9,8%
43	F2585I	0,4833	0,3563		-26,3%
	Mean	0,5657	0,5126		-9,6%
	SEM	0,0177	0,0185	min	-28,0%
	t test vs. T0	---	0,0000	max	4,7%

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director

Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	S0354C	0,6253	0,6536		4,5%
02	G0587G	0,7023	0,6833		-2,7%
03	B0014L	0,4055	0,4111		1,4%
04	F0121F	0,3956	0,4223		6,7%
05	I0170M	0,6674	0,6516		-2,4%
06	M0198G	0,7521	0,7436		-1,1%
07	C0066R	0,8430	0,8502		0,9%
08	B0015R	0,7736	0,7741		0,1%
09	R0329O	0,8012	0,7836		-2,2%
10	P0285R	0,6628	0,6811		2,8%
11	D1967P	0,4566	0,4839		6,0%
12	L1634C	0,5011	0,5084		1,5%
13	P0845G	0,4364	0,4287		-1,8%
14	N0258B	0,5077	0,5011		-1,3%
15	F2070C	0,6236	0,6133		-1,7%
16	B0990C	0,5617	0,5502		-2,0%
17	O1785E	0,6011	0,6082		1,2%
18	V2280A	0,4859	0,5102	VARIATION VS. T0	5,0%
19	G2358M	0,4033	0,3866		-4,1%
20	S2362L	0,7512	0,8011		6,6%
21	R2586L	0,6211	0,6302		1,5%
22	F2587P	0,3617	0,4008		10,8%
23	M2589S	0,4558	0,4602		1,0%
24	R1440V	0,4075	0,3933		-3,5%
25	I2598C	0,5639	0,5802		2,9%
26	C2620D	0,6017	0,5811		-3,4%
27	I2621A	0,4036	0,4236		5,0%
28	G2624I	0,4136	0,4037		-2,4%
29	F2629N	0,5832	0,5545		-4,9%
30	S2630L	0,6033	0,5836		-3,3%
31	B2635A	0,5812	0,6013		3,5%
32	A2654G	0,6039	0,5894		-2,4%
33	D1077A	0,5617	0,6001		6,8%
34	P1606D	0,6311	0,6503		3,0%
35	S2652A	0,6518	0,6021		-7,6%
36	G2367T	0,5811	0,5903		1,6%
37	G2613M	0,4023	0,4128		2,6%
38	G2615B	0,5539	0,5228		-5,6%
39	R2674L	0,6017	0,5801		-3,6%
40	R2660R	0,6536	0,6439		-1,5%
41	A2642S	0,5846	0,6017		2,9%
	Mean	0,5702	0,5720		0,5%
	SEM	0,0191	0,0188	min	-7,6%
	t test vs. T0	---	0,6017	max	10,8%

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director,

Dr Vincenzo Nobile

no.	Vol. ID	T0	T30	VARIATION VS. T0	T30
01	M0701A	23,7368	22,4356		-5,5%
02	S0379S	22,2518	20,5702		-7,6%
03	B0012G	28,3963	33,0204		16,3%
04	B0023B	26,1528	26,2537		0,4%
05	G0135S	33,9376	33,9928		0,2%
06	B1495M	19,4610	19,3310		-0,7%
07	P1529I	17,8413	18,0235		1,0%
08	C0085N	16,2575	17,5629		8,0%
09	P0281E	12,5881	13,2048		4,9%
10	N0270P	19,3490	15,3082		-20,9%
11	G1972E	13,2847	11,0825		-16,6%
12	Z0618R	11,7933	11,5666		-1,9%
13	B1288C	12,6471	12,3937		-2,0%
14	P0282G	16,4833	16,8338		2,1%
15	S0359L	14,4787	16,9224		16,9%
16	L2072M	13,2534	14,7482		11,3%
17	P1979M	21,5388	21,1073		-2,0%
18	V2169I	24,0233	22,0337		-8,3%
19	A2356L	20,9723	16,2904		-22,3%
20	C1620T	19,5037	16,4876		-15,5%
21	A2360R	17,4373	16,7343		-4,0%
22	G2361S	13,6943	14,5070		5,9%
23	M1266R	13,6528	13,9630		2,3%
24	M0760V	16,4142	18,2883		11,4%
25	R2400C	25,3621	24,0320		-5,2%
26	C2404L	20,3611	19,3650		-4,9%
27	Z2405A	27,5300	22,5598		-18,1%
28	P1632E	20,3670	19,6842		-3,4%
29	S0872M	21,0365	20,2536		-3,7%
30	B1081G	18,3650	20,2740		10,4%
31	B2320D	13,3561	14,8831		11,4%
32	G2456A	15,5250	16,0277		3,2%
33	G2455M	24,3650	23,0250		-5,5%
34	G2454L	20,3650	24,0521		18,1%
35	S2140I	18,3527	20,5233		11,8%
36	L1086A	23,6525	26,8754		13,6%
37	E1765A	16,7544	15,3650		-8,3%
38	M1965C	20,3652	22,0363		8,2%
39	F2579C	15,0367	18,0652		20,1%
40	G0824G	18,3650	19,0254		3,6%
41	C1963A	26,7843	25,2630		-5,7%
42	S0869S	20,0212	19,0545		-4,8%
43	F2585I	17,3653	17,5860		1,3%
	Mean	19,3600	19,3166		0,4%
	SEM	0,7560	0,7587	min	-22,3%
	t test vs. T0	---	0,8914	max	20,1%

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director

Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	S0354C	30,2542	31,2520		3,3%
02	G0587G	18,6034	17,6909		-4,9%
03	B0014L	28,0364	25,3236		-9,7%
04	F0121F	15,7362	16,5577		5,2%
05	I0170M	16,3502	17,7088		8,3%
06	M0198G	19,3654	20,0213		3,4%
07	C0066R	13,6895	13,2731		-3,0%
08	B0015R	21,5875	22,0365		2,1%
09	R0329O	20,6696	21,0284		1,7%
10	P0285R	19,8111	19,5157		-1,5%
11	D1967P	15,1208	15,6470		3,5%
12	L1634C	12,2831	13,0820		6,5%
13	P0845G	14,1909	13,5220		-4,7%
14	N0258B	15,7965	16,4598		4,2%
15	F2070C	16,3832	16,6165		1,4%
16	B0990C	15,4613	15,5969		0,9%
17	O1785E	14,3622	15,1948		5,8%
18	V2280A	18,6478	17,7375		-4,9%
19	G2358M	24,4103	28,7524		17,8%
20	S2362L	20,0864	21,1111		5,1%
21	R2586L	18,3650	17,0255		-7,3%
22	F2587P	30,3544	28,3250		-6,7%
23	M2589S	21,1976	22,0365		4,0%
24	R1440V	26,2546	27,0211		2,9%
25	I2598C	20,3649	20,4023		0,2%
26	C2620D	28,3645	29,0236		2,3%
27	I2621A	15,6488	16,0222		2,4%
28	G2624I	18,3656	19,3656		5,4%
29	F2629N	15,5695	16,0221		2,9%
30	S2630L	24,0236	23,8452		-0,7%
31	B2635A	18,9745	17,0213		-10,3%
32	A2654G	15,6747	14,3330		-8,6%
33	D1077A	20,1254	20,8454		3,6%
34	P1606D	18,7598	19,0282		1,4%
35	S2652A	13,1542	12,8456		-2,3%
36	G2367T	28,3364	29,0217		2,4%
37	G2613M	30,1425	31,0242		2,9%
38	G2615B	22,3408	23,2545		4,1%
39	R2674L	30,1433	30,5986		1,5%
40	R2660R	20,1136	23,1785		15,2%
41	A2642S	15,2875	16,0211		4,8%
	Mean	20,0587	20,3510		1,5%
	SEM	0,8252	0,8507	min	-10,3%
	t test vs. T0	---	0,1346	max	17,8%

VARIATION VS. T0

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	M0701A	0,6195	0,7319		18,1%
02	S0379S	0,6509	0,7241		11,2%
03	B0012G	0,6417	0,7084		10,4%
04	B0023B	0,5772	0,7336		27,1%
05	G0135S	0,7096	0,7618		7,4%
06	B1495M	0,6769	0,7321		8,2%
07	P1529I	0,7486	0,7823		4,5%
08	C0085N	0,7186	0,7412		3,1%
09	P0281E	0,6554	0,7164		9,3%
10	N0270P	0,6317	0,7445		17,9%
11	G1972E	0,6098	0,7479		22,6%
12	Z0618R	0,7301	0,7657		4,9%
13	B1288C	0,7055	0,8020		13,7%
14	P0282G	0,5934	0,6462		8,9%
15	S0359L	0,7812	0,8722		11,6%
16	L2072M	0,7185	0,7600		5,8%
17	P1979M	0,6697	0,7030		5,0%
18	V2169I	0,6044	0,6660		10,2%
19	A2356L	0,6589	0,7236		9,8%
20	C1620T	0,6870	0,7015		2,1%
21	A2360R	0,5860	0,6060		3,4%
22	G2361S	0,7018	0,7348		4,7%
23	M1266R	0,6160	0,6380		3,6%
24	M0760V	0,6440	0,6880		6,8%
25	R2400C	0,6531	0,7211		10,4%
26	C2404L	0,6018	0,6580		9,3%
27	Z2405A	0,5890	0,6280		6,6%
28	P1632E	0,6048	0,6481		7,2%
29	S0872M	0,7521	0,7936		5,5%
30	B1081G	0,6823	0,7218		5,8%
31	B2320D	0,6705	0,7256		8,2%
32	G2456A	0,5864	0,6936		18,3%
33	G2455M	0,5819	0,6102		4,9%
34	G2454L	0,5969	0,6311		5,7%
35	S2140I	0,7025	0,8003		13,9%
36	L1086A	0,7336	0,7801		6,3%
37	E1765A	0,6511	0,7036		8,1%
38	M1965C	0,7039	0,7511		6,7%
39	F2579C	0,6802	0,7302		7,4%
40	G0824G	0,7130	0,7836		9,9%
41	C1963A	0,6036	0,6933		14,9%
42	S0869S	0,6896	0,7256		5,2%
43	F2585I	0,6345	0,7836		23,5%
	Mean	0,6597	0,7212		9,5%
	SEM	0,0082	0,0087	min	2,1%
	t test vs. T0	---	0,0000	max	27,1%

VARIATION VS. T0

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	S0354C	0,6936	0,7016		1,2%
02	G0587G	0,6629	0,6825		3,0%
03	B0014L	0,6738	0,6702		-0,5%
04	F0121F	0,5843	0,6239		6,8%
05	I0170M	0,6722	0,6888		2,5%
06	M0198G	0,6739	0,7126		5,7%
07	C0066R	0,7123	0,7203		1,1%
08	B0015R	0,6956	0,7004		0,7%
09	R0329O	0,6367	0,5977		-6,1%
10	P0285R	0,5913	0,6150		4,0%
11	D1967P	0,7090	0,6919		-2,4%
12	L1634C	0,6469	0,6499		0,5%
13	P0845G	0,6830	0,7135		4,5%
14	N0258B	0,6609	0,6783		2,6%
15	F2070C	0,6777	0,6881		1,5%
16	B0990C	0,6703	0,6989		4,3%
17	O1785E	0,6905	0,6529		-5,4%
18	V2280A	0,5730	0,5828		1,7%
19	G2358M	0,5778	0,5723		-1,0%
20	S2362L	0,5640	0,5778		2,4%
21	R2586L	0,6612	0,6730		1,8%
22	F2587P	0,6504	0,6493		-0,2%
23	M2589S	0,5815	0,5894		1,4%
24	R1440V	0,7327	0,7416		1,2%
25	I2598C	0,5947	0,6067		2,0%
26	C2620D	0,7180	0,7209		0,4%
27	I2621A	0,6785	0,6842		0,8%
28	G2624I	0,6145	0,6267		2,0%
29	F2629N	0,7301	0,7409		1,5%
30	S2630L	0,6358	0,6563		3,2%
31	B2635A	0,7333	0,7437		1,4%
32	A2654G	0,7075	0,7205		1,8%
33	D1077A	0,6199	0,6220		0,3%
34	P1606D	0,8332	0,8534		2,4%
35	S2652A	0,7367	0,7419		0,7%
36	G2367T	0,7890	0,7919		0,4%
37	G2613M	0,6565	0,6768		3,1%
38	G2615B	0,7218	0,7317		1,4%
39	R2674L	0,6258	0,6407		2,4%
40	R2660R	0,7289	0,7319		0,4%
41	A2642S	0,6523	0,6626		1,6%
	Mean	0,6696	0,6787		1,4%
	SEM	0,0092	0,0093	min	-6,1%
	t test vs. T0	---	0,0005	max	6,8%

VARIATION VS. T0

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	M0701A	6,07	10,51		73,1%
02	S0379S	5,13	8,80		71,5%
03	B0012G	6,37	7,81		22,6%
04	B0023B	5,62	7,98		42,0%
05	G0135S	4,12	6,69		62,4%
06	B1495M	5,43	7,84		44,4%
07	P1529I	7,57	8,32		9,9%
08	C0085N	3,58	5,06		41,3%
09	P0281E	5,85	6,31		7,9%
10	N0270P	3,19	5,69		78,4%
11	G1972E	6,65	7,35		10,5%
12	Z0618R	6,69	7,03		5,1%
13	B1288C	5,84	6,90		18,2%
14	P0282G	5,33	7,10		33,2%
15	S0359L	8,25	10,04		21,7%
16	L2072M	6,16	10,09		63,8%
17	P1979M	8,30	10,28		23,9%
18	V2169I	10,40	11,60		11,5%
19	A2356L	8,94	10,72		19,9%
20	C1620T	10,81	11,70		8,2%
21	A2360R	9,75	10,88		11,6%
22	G2361S	10,30	11,80		14,6%
23	M1266R	10,05	10,60		5,5%
24	M0760V	10,10	11,30		11,9%
25	R2400C	6,36	8,88		39,6%
26	C2404L	9,66	10,98		13,7%
27	Z2405A	9,66	11,80		22,2%
28	P1632E	10,10	12,90		27,7%
29	S0872M	6,88	7,45		8,3%
30	B1081G	5,36	9,19		71,5%
31	B2320D	10,90	12,98		19,1%
32	G2456A	8,69	10,83		24,6%
33	G2455M	5,11	7,08		38,6%
34	G2454L	6,39	8,90		39,3%
35	S2140I	9,24	9,85		6,6%
36	L1086A	11,30	15,36		35,9%
37	E1765A	8,31	11,03		32,7%
38	M1965C	5,52	6,98		26,4%
39	F2579C	6,84	7,93		15,9%
40	G0824G	8,91	9,89		11,0%
41	C1963A	9,36	11,25		20,2%
42	S0869S	10,33	12,05		16,7%
43	F2585I	10,56	12,08		14,4%
	Mean	7,67	9,53		27,8%
	SEM	0,34	0,35	min	5,1%
	t test vs. T0	---	0,0000	max	78,4%

VARIATION VS. T0

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	S0354C	5,78	6,03		4,3%
02	G0587G	5,19	5,61		8,1%
03	B0014L	4,97	4,72		-5,0%
04	F0121F	6,69	8,94		33,6%
05	I0170M	5,44	5,53		1,7%
06	M0198G	6,21	6,85		10,3%
07	C0066R	5,25	5,65		7,6%
08	B0015R	6,37	5,27		-17,3%
09	R0329O	4,78	4,62		-3,3%
10	P0285R	4,93	5,03		2,0%
11	D1967P	10,34	9,23		-10,7%
12	L1634C	9,42	9,03		-4,1%
13	P0845G	4,00	4,75		18,8%
14	N0258B	5,19	5,80		11,8%
15	F2070C	5,12	5,72		11,7%
16	B0990C	4,84	5,06		4,5%
17	O1785E	6,66	6,71		0,8%
18	V2280A	8,20	8,40		2,4%
19	G2358M	7,11	7,09	VARIATION VS. T0	-0,3%
20	S2362L	10,05	10,60		5,5%
21	R2586L	9,99	11,12		11,3%
22	F2587P	10,05	10,15		1,0%
23	M2589S	10,04	10,72		6,8%
24	R1440V	11,78	11,85		0,6%
25	I2598C	10,01	10,80		7,9%
26	C2620D	9,80	10,03		2,3%
27	I2621A	9,54	9,68		1,5%
28	G2624I	10,11	10,45		3,4%
29	F2629N	10,32	10,71		3,8%
30	S2630L	11,20	11,41		1,9%
31	B2635A	9,71	10,12		4,2%
32	A2654G	10,71	11,21		4,7%
33	D1077A	10,23	10,82		5,8%
34	P1606D	8,44	8,74		3,6%
35	S2652A	8,10	8,26		2,0%
36	G2367T	11,20	11,40		1,8%
37	G2613M	10,30	10,44		1,4%
38	G2615B	9,77	10,12		3,6%
39	R2674L	10,12	10,22		1,0%
40	R2660R	8,32	8,53		2,5%
41	A2642S	5,54	5,80		4,7%
	Mean	8,09	8,37		3,8%
	SEM	0,37	0,37	min	-17,3%
	t test vs. T0	---	0,0016	max	33,6%

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	M0701A	45,0	50,2		11,6%
02	S0379S	45,0	50,4		12,0%
03	B0012G	52,1	63,9		22,6%
04	B0023B	41,1	54,3		32,1%
05	G0135S	46,8	53,8		15,0%
06	B1495M	38,6	50,2		30,1%
07	P1529I	37,3	47,3		26,8%
08	C0085N	49,2	58,3		18,5%
09	P0281E	42,5	48,1		13,2%
10	N0270P	51,4	61,1		18,9%
11	G1972E	52,3	63,3		21,0%
12	Z0618R	50,3	65,4		30,0%
13	B1288C	45,4	58,5		28,9%
14	P0282G	50,2	58,6		16,7%
15	S0359L	50,4	58,3		15,7%
16	L2072M	52,6	59,8		13,7%
17	P1979M	32,1	35,8		11,5%
18	V2169I	36,8	40,1		9,0%
19	A2356L	35,9	44,3		23,4%
20	C1620T	34,1	39,9	VARIATION VS. T0	17,0%
21	A2360R	29,5	31,4		6,4%
22	G2361S	30,5	32,4		6,2%
23	M1266R	29,9	31,4		5,0%
24	M0760V	29,8	31,5		5,7%
25	R2400C	35,1	42,3		20,5%
26	C2404L	30,1	35,1		16,6%
27	Z2405A	28,4	33,1		16,5%
28	P1632E	39,8	45,8		15,1%
29	S0872M	30,3	36,2		19,5%
30	B1081G	42,2	45,5		7,8%
31	B2320D	29,0	39,0		34,5%
32	G2456A	36,6	45,5		24,3%
33	G2455M	45,5	50,2		10,3%
34	G2454L	50,6	55,4		9,5%
35	S2140I	31,8	35,2		10,7%
36	L1086A	33,2	45,5		37,0%
37	E1765A	46,8	60,3		28,8%
38	M1965C	50,7	56,3		11,0%
39	F2579C	45,5	53,4		17,4%
40	G0824G	30,2	33,2		9,9%
41	C1963A	28,6	34,1		19,2%
42	S0869S	34,5	45,2		31,0%
43	F2585I	30,2	38,2		26,5%
	Mean	**39,7**	**46,9**		**18,1%**
	SEM	1,3	1,6	min	5,0%
	t test vs. T0	---	0,0000	max	37,0%

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director

Dr Vincenzo Nobile

no.	Vol. ID	T0	T30		T30
01	S0354C	50,9	53,6		5,3%
02	G0587G	50,7	52,6		3,7%
03	B0014L	37,9	43,3		14,2%
04	F0121F	51,7	56,2		8,7%
05	I0170M	50,6	52,6		4,0%
06	M0198G	50,8	56,5		11,2%
07	C0066R	47,0	54,9		16,8%
08	B0015R	46,9	51,4		9,6%
09	R0329O	40,4	50,4		24,8%
10	P0285R	51,3	55,8		8,8%
11	D1967P	48,5	52,3		7,8%
12	L1634C	40,4	43,4		7,4%
13	P0845G	48,7	54,6		12,1%
14	N0258B	46,6	50,4		8,2%
15	F2070C	42,7	48,8		14,3%
16	B0990C	44,8	50,6		12,9%
17	O1785E	50,2	46,2		-8,0%
18	V2280A	30,9	31,1		0,8%
19	G2358M	30,2	29,5		-2,2%
20	S2362L	32,7	33,3		1,8%
21	R2586L	34,1	35,5		4,1%
22	F2587P	32,8	33,3		1,4%
23	M2589S	37,5	38,1		1,7%
24	R1440V	29,8	30,2		1,3%
25	I2598C	34,5	37,2		7,9%
26	C2620D	27,2	27,8		2,2%
27	I2621A	39,5	42,3		7,1%
28	G2624I	34,9	35,1		0,6%
29	F2629N	25,9	26,3		1,5%
30	S2630L	33,5	34,7		3,6%
31	B2635A	33,8	34,2		1,2%
32	A2654G	34,9	36,2		3,7%
33	D1077A	34,3	35,2		2,6%
34	P1606D	33,7	34,2		1,4%
35	S2652A	37,0	38,2		3,2%
36	G2367T	34,3	34,9		1,7%
37	G2613M	38,4	39,7		3,4%
38	G2615B	33,7	34,1		1,2%
39	R2674L	35,4	37,2		5,1%
40	R2660R	30,6	32,7		6,9%
41	A2642S	25,5	26,2		2,7%
	Mean	38,9	41,2		5,5%
	SEM	1,2	1,5	min	-8,0%
	t test vs. T0	---	0,0000	max	24,8%

VARIATION VS. T0

All data and supporting documentation for this study have been audited and found to be accurate, complete and in compliance with the requirements of the protocol and Farcoderm srl Standard Operative Instructions. The data here above reported have been reviewed and accurately reflects the raw data.

The study director
Dr Vincenzo Nobile