

Clinical Trial on Nature Nuskha Day Care & Night Care Hair Therapy

Title: Efficacy and Safety of the Nature Nuskha Day Care & Night Care Hair Therapy to control Hair Fall, Premature Graying of Hair & Dandruff in various scalp conditions.

Name and Address of the Sponsor:

IQGEN-X Pharma Pvt. Ltd. Navi Mumbai. INDIA

Name and Address of Clinical Trial Institute:

S.R.M. State Ayurvedic Medical College & Hospital
Bareilly (U.P.) INDIA

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1. INTRODUCTION:

Hair loss, or Alopecia, is a concern for men, women, and children. Hair loss can be an indication of some serious health issues like heart disease, diabetes mellitus, ovarian cysts, thyroid and autoimmune disorders. It also has a negative impact on social life and can lead to depression. Do not neglect hair loss. Treatments for hair loss include medications such as Propecia and Rogaine, hair replacements, and hair restoration.

2. BACKGROUND

2.1 ALOPECIA AREATA

If you've seen a lot of extra hair on your pillow, brush, or shower drain, or you've noticed odd little bald spots in the mirror, you might have an autoimmune disorder called alopecia areata.

When you have an autoimmune disease, your immune system attacks your own body. With alopecia areata, it's the hair follicles that are attacked. This causes the hair to come out, often in

clumps the size and shape of a quarter. The amount of hair loss is different in everyone. Some people lose it only in a few spots. Others lose a lot.

It's rare, but you can lose all the hair on your head (alopecia areata totalis) or entire body (alopecia areata universalis).

Each case of alopecia areata is different. Sometimes, hair grows back but falls out again later. In others, hair grows back for good.

Understanding Hair Loss -- the Basics: What Is Hair Loss?

Hair grows everywhere on the human skin except on the palms of our hands and the soles of our feet, but many hairs are so fine they're virtually invisible. Hair is made up of a protein called keratin that is produced in hair follicles in the outer layer of skin. As follicles produce new hair cells, old cells are being pushed out through the surface of the skin at the rate of about six inches a year. The hair you can see is actually a string of dead keratin cells. The average adult head has about 100,000 to 150,000 hairs and loses up to 100 of them a day; finding a few stray hairs on your hairbrush is not necessarily cause for alarm.

At any one time, about 90% of the hair on a person's scalp is growing. Each follicle has its own life cycle that can be influenced by age, disease, and a wide variety of other factors. This life cycle is divided into three phases:

- Anagen -- active hair growth that lasts between two to six years
- Catagen -- transitional hair growth that lasts two to three weeks
- Telogen -- resting phase that lasts about two to three months; at the end of the resting phase the hair is shed and a new hair replaces it and the growing cycle starts again.

Understanding Hair Loss Signs & Symptoms: What Are the Signs of Hair Loss?

Signs of hair loss and hair loss conditions vary between men, women and children. However, people of any age or sex may notice more hair collecting in their hairbrush or in the shower drain.

The signs of hair loss and hair conditions in men may include:

- Thinning hair on the scalp
- A receding hairline
- A horseshoe-shaped pattern that leaves the crown of the head exposed
- Signs of hair loss and hair conditions in women may include:
- General hair thinning, especially at the crown of the head

Women and Hair Loss: Possible Causes

His best way to think of the way hair grows is to picture a garden. How well it grows is completely a result of what is happening "underground."

"Like a garden, a normal hair cycle should lead to a product, which is the hair," says Wendy Roberts, a dermatologist at a private practice in Rancho Mirage, Calif. "Growth cycles are important because when they go awry, that is one of the reasons we have hair loss."

And things that interfere with the cycle -- like medication, illness, infection, or chemicals -- have the potential to stop hair from being formed properly.

TELOGEN EFFLUVIUM AND OTHER EFFLUVIUMS

Some hair loss conditions go by the name "effluvium," which means an outflow. Effluviums characteristically affect different phases of the hair growth cycle.

Hair follicles on the scalp do not continuously produce hair. They cycle through a growth stage that can last two or more years, then regress to a resting stage for up to two months before starting to grow a new hair fiber again. At any time on a healthy human scalp, about 80% to 90% of the hair follicles are growing hair. These active follicles are in what is called the anagen phase. That leaves up to 10% to 20% percent of scalp hair follicles in a resting state called telogen, when they don't produce any hair fiber.

Telogen Effluvium

Telogen effluvium (TE) is probably the second most common form of hair loss dermatologists see. It is a poorly defined condition; very little research has been done to understand TE. In essence though, TE happens when there is a change in the number of hair follicles growing hair. If the number of hair follicles producing hair drops significantly for any reason during the resting, or telogen phase, there will be a significant increase in dormant, telogen stage hair follicles. The result is shedding, or TE hair loss

HAIR LOSS: INFECTIOUS AGENTS

A number of infectious agents and infection-related conditions can contribute to hair loss. Some common ones are described here.

Ringworm Infections

Surprisingly, ringworm has nothing to do with worms, but is a fungal infection that can occur anywhere on the body. If it develops on the scalp, it can cause patches of hair loss and is known to doctors as "tinea capitis." Ringworm is the same thing as athlete's foot, and the same kind of fungal infection that can affect the nails too.

On the scalp, ringworm usually begins as a small pimple that progressively expands in size, leaving scaly patches of temporary baldness. The fungus gets into the hair fibers in the affected area and these hairs become brittle and break off easily, leaving a bald patch of skin. Affected areas are often itchy, red, and inflamed, with scaly patches that may blister and ooze. The patches are usually redder around the outside with a more normal skin tone in the center. This may create the appearance of a ring -- hence the name, ringworm.

SCALP PROBLEMS

Your scalp often plays second fiddle to your hair. Until it starts begging for attention, that is. With several common conditions, your scalp may itch and get irritated.

Dandruff

Little white flakes signal an old-fashioned case of dandruff. It can be annoying when the flakes fall on a dark shirt. Dandruff is simply a buildup of shedding dead skin. We don't know the cause, but it may be due to a fungus on the skin.

You can't catch dandruff from someone else, and it isn't dangerous, but it can be itchy and a bother. Luckily, there's no redness or scabbing of the scalp. you may need to try two or three products to clear up your dandruff.

Seborrheic Dermatitis

Dandruff is a mild form of seborrheic dermatitis. In more severe cases, you'll see a reddening of the scalp and a lot of oil. The result is a greasy look and feel. According to the American Academy of Dermatology, it's common in those with oily skin or hair, acne, or psoriasis.

Cradle Cap

This form of seborrheic dermatitis affects infants, typically in the first 6 months. It causes greasy, yellowish scales or crusts on the scalp. Although it may frighten parents, cradle cap is not a sign of a more serious infection, and it will usually clear up by the baby's first birthday.

Scarring Alopecia

Scarring alopecia, also known as cicatricial alopecia, refers to a collection of hair loss disorders that may be diagnosed in up to 3% of hair loss patients. It occurs worldwide in otherwise healthy men and women of all ages.

Each specific diagnosis within this category is fairly rare, but some examples include dissecting cellulitis, eosinophilic pustular folliculitis, follicular degeneration syndrome (previously called "hot comb" alopecia), folliculitis decalvans, lichen planopilaris, and pseudopelade of Brocq, to name a few. Scarring alopecia may also be part of a much larger condition such as chronic lupus erythematosus, where many organs of the body can be affected.

While there are many forms of scarring alopecia, the common theme is a potentially permanent and irreversible destruction of hair follicles and their replacement with scar tissue.

Most forms of scarring alopecia first occur as small patches of hair loss that may expand with time. In some cases the hair loss is gradual, without noticeable symptoms, and may go unnoticed for a long time. In other instances, the hair loss is associated with severe itching, burning, and pain, and is rapidly progressive.

The scarring alopecia patches usually look a little different from alopecia areata in that the edges of the bald patches look more "ragged." The destruction of the hair follicle occurs below the skin surface so there may not be much to actually see on the scalp skin surface other than patchy hair loss. Affected areas may be smooth and clean, or may have redness, scaling, increased or decreased pigmentation, or may have raised blisters with fluids or pus coming from the affected area.

These visual indicators may help with diagnosis, but it is difficult to diagnose a scarring alopecia just from the pattern of the hair loss and the nature of the scalp skin. Often when scarring alopecia is suspected, one or more skin biopsies are done to confirm the diagnosis and help identify the particular form of scarring alopecia. A small biopsy of 2 to 4 mm in diameter is taken and examined under a microscope. A pathologist or dermatologist will look for destruction

of the hair follicles, scar tissue deep in the skin, and the presence and location of inflammation in relation to the hair follicles.

2.2 ABOUT NATURE NUSKHA DAY CARE AND NIGHT CARE THERAPY

2.2.1 Various Herbs Used viz.

Herbal Hair Tonic Nature Nuskha Day Therapy- Natural; Herbal Extract of Peas, Brahmi, Bhringraj, Shankpushpi, Bahera, Neem and Glycerine.

Herbal Hair Tonic Nature Nuskha Night Therapy- Natural; Oil Extract of Avocado, Jojoba, Flex seed, Coconut, Sesame, Mustard, Clove, Orange peel, Cardamom Oil, Natural Tocopherols, Peas and Neem Extract.

The Nature Nuskha Day Therapy and Night Therapy Products are Oil Extract based and Non-Oil Herbal Extract based Day Care Therapy and Night Care Hair Therapy should give the following results if regularly used. They were formulated as Hair Care Therapy solutions.

Benefits of Nature Nuskha Day Therapy-

- ✓ Acts as a natural screen against sunlight and pollutants
- ✓ Prevents untimely hair ageing
- ✓ Reduced dandruff
- ✓ Improves scalp moisturized
- ✓ Improves hair strength and density

Benefits of Nature Nuskha Night Scalp Therapy-

- ✓ Removes dandruff
- ✓ Controls hair fall and enhances hair growth
- ✓ Promotes hair re-growth
- ✓ Prevents untimely graying of hair
- ✓ Improves hair quality and strength

The Common therapy of above will show beneficial effect on the problems of **Hair Fall**, **Premature Graying of Hair** & **Dandruff** and promotes **Hair growth** and **Hair re-growth** in the age group of 16-40 across the gender.

3. STUDY RATIONALES:

Hair loss, or Alopecia, is a concern for men, women, and children. Hair loss can be an indication of various serious health issues including autoimmune disorders. It also has a negative impact on social life and can lead to depression. Do not neglect hair loss.

The herbal ingredients used in these herbal hair tonics have been used in the treatment of various scalp diseases. Their long standing use in human beings is a testimony of their use. Their

efficacy in the treatment of Hair loss, or Alopecia Dandruff and Hair Graying was assessed in various ancient literature reviews.

The efficacy of these herbs singly and in combination has been established by Researcher at **IQGEN-X Pharma Pvt. Ltd. Navi Mumbai**. There after the herbal combination chosen after various studies has been exposed to appropriate studies. As the Internationally accepted norms, we wish to undertake the formulation to Phase II clinical trial of the Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit.

3.1 OBJECTIVES

Phase II:

3.2 Primary Objective:

- a.** To determine the efficacy of Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit for achieving the target to control Hair Fall, Premature Graying of Hair & Dandruff and promotes Hair growth and Hair re-growth in the age group of 16-40 across the gender.
- b.** To assess the appropriate strength of the formulation with dose and duration for present subsequent study.

3.3 Secondary Objective:

A. To determine the tolerability and safety of Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit.

4. STUDY DESIGN

The study will be conducted at single site inpatient hospital of **SRM Government Ayurvedic Medical College & Hospital, Bareilly** and Combination Scalp Treatment with Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit study and with Separately Single Scalp Treatment study with Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy respectively.

After assessing the efficacy of the study, the dose response determination was conducted in three different therapies. Based on the results potential study end points and the target population will be determined.

The study was conducted in healthy individuals between 16 to 40 years of age across the gender. The study will be conducted in 148 volunteers. Out of 148 volunteers only 115 were completed the study. Three groups of 48, 48 & 49 patients of hair care tonic were evaluated respectively.

Three therapy of Herbal Hair Tonic was tried i.e. Combination Scalp Treatment with Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit, Separately Single Scalp Treatment study with Herbal Hair Tonic Nature Nuskha Day Therapy and Separately Single Scalp Treatment study with Herbal Hair Tonic Nature Nuskha Night Therapy.

Each group was receive either of these scalp therapies. First tolerability and efficacy was assessed with combination scalp treatment with Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit as per the design explained below.

It was a single blind parallel design study where different strengths of the drug were evaluated simultaneously.

Randomization was done using ‘Outcome-adaptive randomization procedure. Concealment will be done using Sequentially-Numbered, Opaque, Sealed Envelopes (SNOSE)

The volunteers were undertaken various complaints of hair and scalp examination of volunteers and the enrolled in the study.

Study Population:

Subjects of between 16 to 40 years of age across the gender

Number of Patients:

Total 115 patients have completed the Phase II study with three groups of G-1: 48, G-2:48 & G3: 49 subjects of hair care tonic were evaluated respectively.

Eligibility Criteria:

Inclusion criteria-

Those who have Hair Fall, Premature Graying of Hair and Dandruff Scalp Conditions

Exclusion Criteria-

1. Having any extra scalp disease.
2. Having associated systemic disease.

Primary End Point: Effect on Scalp Condition

On inclusion of the patient, suggested dose was applied on the scalp and the findings were recorded.

Therapy Group 1 (Combination Scalp Treatment with Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit)

Therapy Group 2 (Single Scalp Treatment study with Herbal Hair Tonic Nature Nuskha Day Therapy)

Therapy Group 3 (Single Scalp Treatment study with Herbal Hair Tonic Nature Nuskha Night Therapy)

After initial assessment of tolerability and efficacy after administration of the drug was evaluated on the basis of its ability to reduce in percentage, at screening after 2nd week, 4th weeks, 6th

weeks, 8th weeks 10th weeks and after 12th weeks and the findings were recorded in a table as shown under:

Parameters	Observation After						
	Initially	2 st Week	4 nd Week	6 th Week	8 th Week	10 th Week	12 th Week
Condition of Scalp 1. Hair Fall							
Hair Density							
Hair thickness							
Hair length							
Linear growth rate							
2. Premature Graying of Hair							
3. Dandruff							
Any other Observation [Questionnaire] Growth of hair/Amount of noticeable new hair/ Visibility of the scalp/ Rate of hair loss							

Grading Scale: Grade from **5 maximum to 1 minimize** for main ailments of scalps conditions or from **1 minimum to 5 maximize** for hair related improvement assessment

Secondary End Point:

1. Scalps Screening

Grading of Scalp and Hair condition will be screening by taken snap shot

	At inclusion	At the end of the treatment 12 th Week
Grade		

2. Allergic Conditions

	Initial	After one month treatment 12 th Week
Grade		

Material and Methods:

The following two Nature Nuskha Day Care Therapy and Night Care Therapy Kit were supplied by the sponsor in 90ml vials:

Herbal Hair Tonic Nature Nuskha Day Therapy- Natural; Herbal Extract of Peas, Brahmi, Bhringraj, Shankhpushpi, Bahera, Neem and Glycerine.

Herbal Hair Tonic Nature Nuskha Night Therapy- Natural; Oil Extract of Avocado, Jojoba, Flex seed, Coconut, Sesame, Musterd, Clove, Orange peel, Cardamom Oil, Natural Tocopheroles, Peas and Neem Extract.

SUBJECT SELECTION

The subjects were selected as per the inclusion criteria randomly by the investigator through organizing eye check up camps and routine OPD. The subjects underwent standardized screening procedure as described in the inclusion and exclusion criteria.

Screening Assessment:

Medical histories, demographic data, name, age, sex, and blood sugar levels were recorded. Only the subjects who qualified the assessment criteria were included in the study.

Tests:

The subjects were asked to undergo the following blood examinations at the time of inclusion and after the completion of the study. Blood: Hb%, ESR, Random Blood Sugar, Blood Urea & Serum Bilirubin for safety profile of trial.

Study Conduct:

The study was conducted at the OPD and Camps held at S.R.M. State Ayurvedic Medical College & Hospital Bareilly (U.P.) by Dr. Santosh Kumar, Principal Investigator and Dr. Atul Kumar Co-investigator of the study. The patients were screened routinely in the OPD/Camps and investigated as per protocol and included in the study. Nature Nuskha Day Care Therapy and Night Care Therapy Kit were used and evenly distributed one by one in the subjects enrolled in the study.

Study Treatment:

Subjects included in the study were visited in the hospital and different strengths of Herbal Hair Tonic Nature Nuskha was evaluated the Improve Various Scalp Condition in Hair Fall, Premature Graying of Hair and Dandruff from the base level of Scalp Condition by tested therapy in following Therapy Group with Herbal Hair Tonic Nature Nuskha Treatment were applied on the scalp as suggested.

Therapy Group 1 (Combination Scalp Treatment with Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit) **was applied on the scalp twice, Nature Nuskha Day Therapy in the Morning after bath and Night Therapy at Night before sleep respectively.**

Therapy Group 2 (Single Scalp Treatment study with Herbal Hair Tonic Nature Nuskha Day Therapy) **was applied on the scalp once, Nature Nuskha Day Therapy in the Morning after bath only.**

Therapy Group 3 (Single Scalp Treatment study with Herbal Hair Tonic Nature Nuskha Night Therapy) **was applied on the scalp once, Night Therapy at Night before sleep only.**

Efficacy of the drug will be evaluated on the basis of its ability to reduce in percentage. Therapy will be instilled taken at screening after 2nd week, 4th weeks, 6th weeks, 8th weeks 10th weeks and after 12th weeks.

Data generated after the administration of the drug in a manner described in Section 4, study design and its recorded effect on Various Scalp Condition in Hair Fall, Premature Graying of Hair and Dandruff will be statistically analyzed and evaluated

Assessment of data recorded on inclusion will be evaluated after 2nd week for the individual patient and after 12th weeks the complete data on all the 115 patients have been completed

Expiry of Formulation:

2 years from the date of manufacturing.

Dose Modification for Study Dose Toxicity:

No case with continued irritation/ redness or any serious adverse effect was noticed during the treatment which could be attributed to the administration of drug so dose modification was not required.

Possible Drug Interactions:

No known drug interaction information available.

Drug Supply: The investigator was supplied with samples marked with different colors on the vials to make differentiation between the two strengths used in the study.

Storage requirement:

Store in cool & dry place at a temperature up to 25 C away from heat and light

Dispensing requirements:

Use within 30 days after opening the vial.

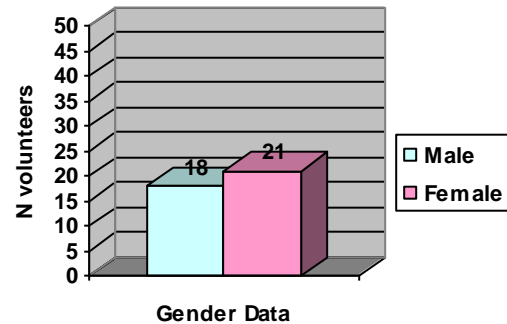
Results & Discussion:**Phase-2 Clinical Trial Report of Nature Nuskha Day Care & Night Care Hair Therapy****VOLUNTEERS ENROLLED:**

TOTAL VOLUNTEERS ENROLLED FOR PHASE-2 CLINICAL TRIAL OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY	
N Volunteers Enrolled	148
N Dropouts	33
Total Volunteers Completed the Trial	115

TOTAL VOLUNTEERS COMPLETED THE TRIAL FOR PHASE-2 CLINICAL TRIAL OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY	
N Volunteers Group-1	38
N Volunteers Group-2	38
N Volunteers Group-3	39
Total Volunteers Completed the Trial	115

VOLUNTEERS ENROLLED FOR NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)	
N Volunteers Completed the Trial	38
N Dropouts	10

GENDER DATA OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)	
N volunteers	38
Male	16
Female	22

GENDER DATA OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

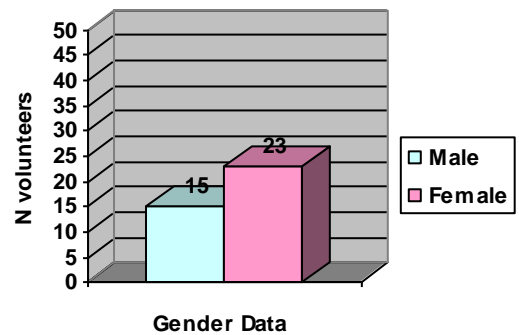
Male	18
Female	21

VOLUNTEERS ENROLLED FOR NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)

N Volunteers Completed the Trial	38
N Dropouts	12

GENDER DATA OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)

N volunteers	38
Male	15
Female	23

GENDER DATA OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)

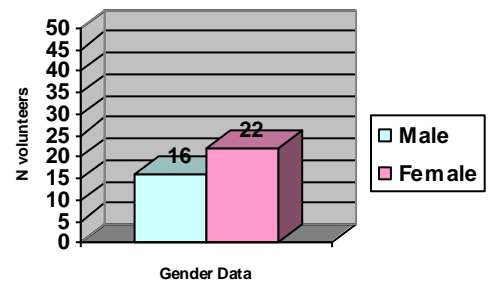
Male	15
Female	23

VOLUNTEERS ENROLLED FOR NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

N Volunteers Completed the Trial	39
N Dropouts	11

GENDER DATA OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

N volunteers	39
Male	18
Female	21

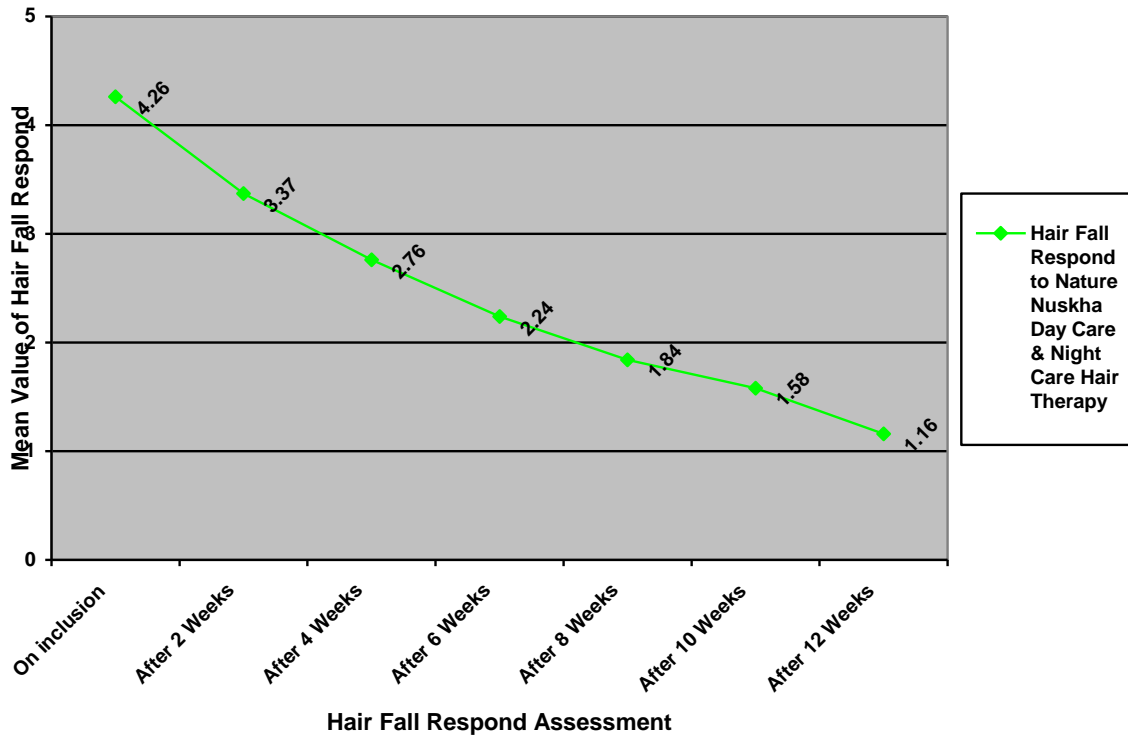
GENDER DATA OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)

Male	16
Female	22

*Primary End Point: Effect on Various Scalp Condition-***PRIMARY END POINT-HAIR FALL ASSESSMENT OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)**

Identification Number	1. Hair Fall						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10374	4	3	2	2	1	1	1
1/10327	5	4	3	2	2	1	1
4/4334	4	3	2	2	1	1	1
4/4446	5	5	3	3	2	2	1
4/4459	4	3	2	2	1	1	1
4/4460	4	3	2	1	1	1	1
4/4452	4	4	3	2	1	1	1
4/4461	4	4	3	2	1	1	1
4/4451	4	3	2	2	1	1	1
7/915	4	2	2	1	1	1	1
4/4518	4	4	3	3	2	2	1
4/4490	4	3	2	1	1	1	1
4/4822	5	4	4	4	4	4	3
4/4238	5	3	2	2	2	1	1
4/4830	4	3	2	2	2	1	1
4/4330	4	4	3	2	2	2	1
1/11117	5	4	4	3	3	2	1
4/5117	5	4	3	2	2	2	1
4/5233	5	4	3	3	2	2	1
4/5221	5	4	4	3	3	3	2
4/5289	5	3	3	2	2	1	1
4/5326	5	4	4	3	3	2	2
4/5313	3	2	2	2	1	1	1
4/5318	4	2	2	1	1	1	1
4/5330	3	3	2	2	2	2	1
4/5343	5	4	3	2	2	2	1
4/5342	3	2	2	1	1	1	1
4/5341	3	2	2	2	1	1	1
4/5523	4	4	3	3	2	1	1
4/5694	5	4	4	3	2	2	1
4/84	3	2	2	2	2	2	1
4/458	5	4	4	3	3	2	1
4/497	3	3	2	2	2	1	1
4/558	5	4	3	2	2	2	1
4/684	4	3	3	2	2	2	1
4/770	4	3	3	3	2	2	2
4/830	5	4	4	3	3	2	2
4/925	5	4	3	3	2	2	1
Mean Value	4.26	3.37	2.76	2.24	1.84	1.58	1.16
Std. Dev.	0.72	0.79	0.75	0.71	0.75	0.68	0.44

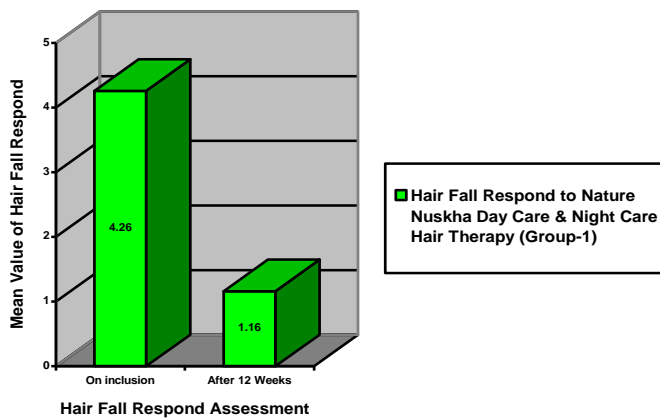
Assessment of Hair Fall Respond to Nature Nuskha Day Care & Night Care Hair Therapy (Group-1)



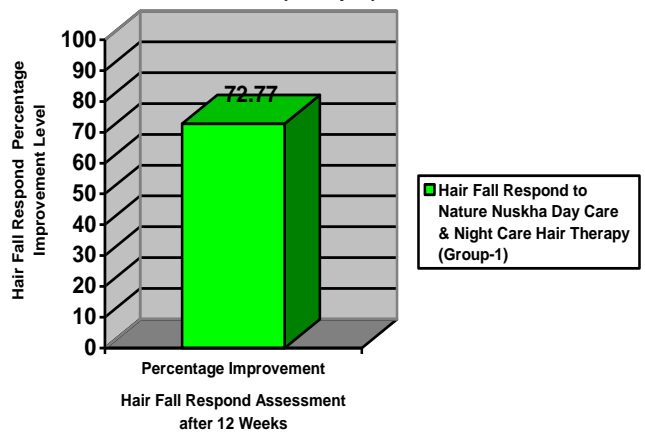
PRIMARY END POINT-HAIR FALL ASSESSMENT OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)							
Hair Fall Measures		N volunteers	Mean	S.D.	Hair Fall Assessment		
On inclusion		38	4.26	0.72	Improvement by	3.1	
After 12 Weeks		38	1.16	0.44	% Improvement	72.77	
t-value		22.64714681					
P-value (as compare to base line)		< 0.05 (S***)					

S = Significant (<0.05) ; NS = Not Significant (>0.05)

Assessment of Hair Fall Respond to Nature Nuskha Day Care & Night Care Hair Therapy (Group-1)



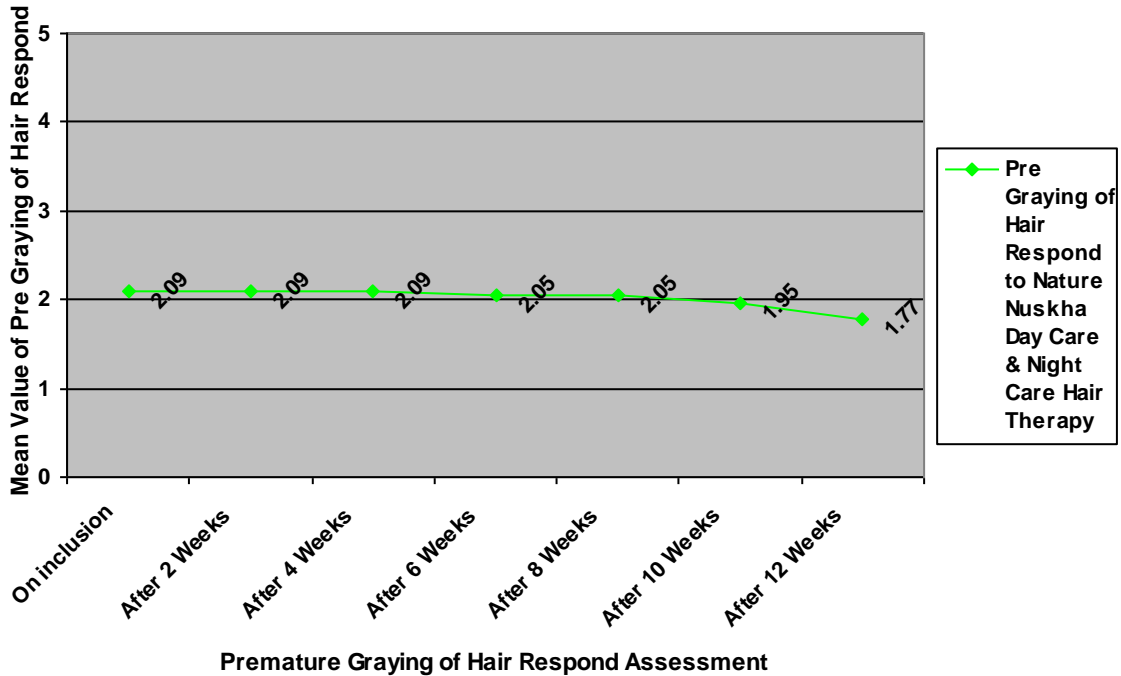
Assessment of Hair Fall Respond to Nature Nuskha Day Care & Night Care Hair Therapy (Group-1)



PRIMARY END POINT-PREATURE GRAYING OF HAIR ASSESSMENT OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)

Identification Number	2. Premature Graying of Hair						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10374	NA	NA	NA	NA	NA	NA	NA
1/10327	NA	NA	NA	NA	NA	NA	NA
4/4334	NA	NA	NA	NA	NA	NA	NA
4/4446	NA	NA	NA	NA	NA	NA	NA
4/4459	NA	NA	NA	NA	NA	NA	NA
4/4460	NA	NA	NA	NA	NA	NA	NA
4/4452	2	2	2	2	2	2	1
4/4461	2	2	2	2	2	1	1
4/4451	NA	NA	NA	NA	NA	NA	NA
7/915	3	3	3	2	2	2	2
4/4518	2	2	2	2	2	2	2
4/4490	NA	NA	NA	NA	NA	NA	NA
4/4822	NA	NA	NA	NA	NA	NA	NA
4/4238	2	2	2	2	2	2	1
4/4830	2	2	2	2	2	2	2
4/4330	2	2	2	2	2	2	2
1/11117	3	3	3	3	3	3	3
4/5117	2	2	2	2	2	2	2
4/5233	NA	NA	NA	NA	NA	NA	NA
4/5221	NA	NA	NA	NA	NA	NA	NA
4/5289	3	3	3	3	3	2	2
4/5326	NA	NA	NA	NA	NA	NA	NA
4/5313	NA	NA	NA	NA	NA	NA	NA
4/5318	NA	NA	NA	NA	NA	NA	NA
4/5330	3	3	3	3	3	3	3
4/5343	2	2	2	2	2	2	2
4/5342	NA	NA	NA	NA	NA	NA	NA
4/5341	2	2	2	2	2	2	2
4/5523	1	1	1	1	1	1	1
4/5694	3	3	3	3	3	3	2
4/84	2	2	2	2	2	2	2
4/458	1	1	1	1	1	1	1
4/497	2	2	2	2	2	2	1
4/558	NA	NA	NA	NA	NA	NA	NA
4/684	1	1	1	1	1	1	1
4/770	2	2	2	2	2	2	2
4/830	2	2	2	2	2	2	2
4/925	2	2	2	2	2	2	2
Mean Value	2.09	2.09	2.09	2.05	2.05	1.95	1.77
Std. Dev.	0.61	0.61	0.61	0.58	0.58	0.58	0.61

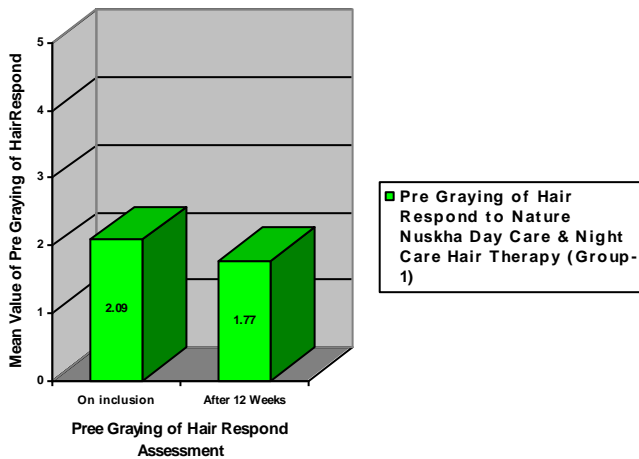
Assessment of Premature Graying of Hair Respond to Nature Nuskha Day Care & Night Care Hair Therapy (Group-1)



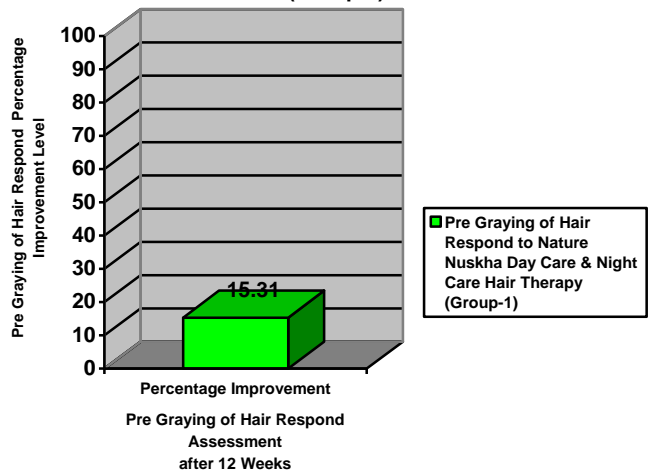
PRIMARY END POINT-PREATURE GRAYING OF HAIR ASSESSMENT OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)					
Premature Graying Hair Measures	N volunteers	Mean	S.D.	Premature Graying of Hair Assessment	
On inclusion	22	2.09	0.61	Improvement by	0.32
After 12 Weeks	22	1.77	0.61	% Improvement	15.31
	t-value	1.739868742			
	P-value (as compare to base line)	> 0.05 (NS)			

S = Significant (<0.05) ; NS = Not Significant (>0.05)

Assessment of Pre Graying of Hair Respond to Nature Nuskha Day Care & Night Care Hair Therapy (Group-1)



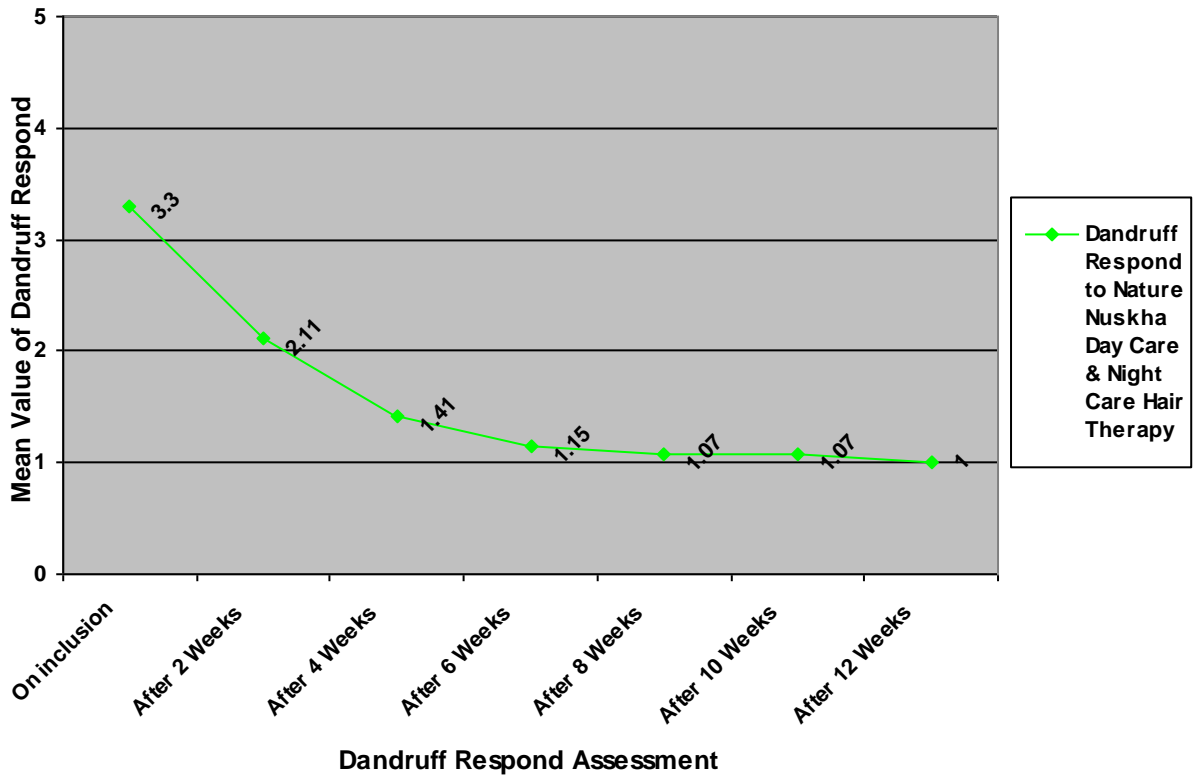
Assessment of Pre Graying of Hair Respond to Nature Nuskha Day Care & Night Care Hair Therapy (Group-1)



PRIMARY END POINT-DANDRUFF ASSESSMENT OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)

Identification Number	3. Dandruff						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10374	NA	NA	NA	NA	NA	NA	NA
1/10327	4	2	1	1	1	1	1
4/4334	NA	NA	NA	NA	NA	NA	NA
4/4446	3	1	1	1	1	1	1
4/4459	NA	NA	NA	NA	NA	NA	NA
4/4460	4	3	2	1	1	1	1
4/4452	4	2	2	1	1	1	1
4/4461	3	2	1	1	1	1	1
4/4451	4	3	2	1	1	1	1
7/915	4	2	1	1	1	1	1
4/4518	3	2	1	1	1	1	1
4/4490	2	1	1	1	1	1	1
4/4822	NA	NA	NA	NA	NA	NA	NA
4/4238	NA	NA	NA	NA	NA	NA	NA
4/4830	NA	NA	NA	NA	NA	NA	NAD
4/4330	3	2	1	1	1	1	1
1/11117	4	3	2	1	1	1	1
4/5117	3	2	1	1	1	1	1
4/5233	3	2	2	2	1	1	1
4/5221	3	2	1	1	1	1	1
4/5289	2	1	1	1	1	1	1
4/5326	NA	NA	NA	NA	NA	NA	NA
4/5313	3	2	1	1	1	1	1
4/5318	3	1	1	1	1	1	1
4/5330	4	3	2	2	2	2	1
4/5343	NA	NA	NA	NA	NA	NA	NA
4/5342	NA	NA	NA	NA	NA	NA	NA
4/5341	3	2	1	1	1	1	1
4/5523	NA	NA	NA	NA	NA	NA	NA
4/5694	4	3	2	2	2	2	1
4/84	3	2	1	1	1	1	1
4/458	4	3	2	2	1	1	1
4/497	3	2	2	1	1	1	1
4/558	3	2	2	1	1	1	1
4/684	NA	NA	NA	NA	NA	NA	NA
4/770	3	2	1	1	1	1	1
4/830	3	2	1	1	1	1	1
4/925	4	3	2	1	1	1	1
Mean Value	3.30	2.11	1.41	1.15	1.07	1.07	1.00
Std. Dev.	0.61	0.64	0.50	0.36	0.27	0.27	0.00

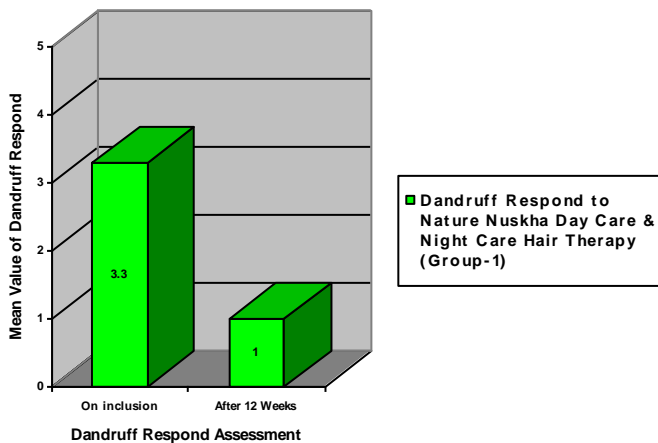
Assessment of Dandruff Respond to Nature Nuskha Day Care & Night Care Hair Therapy (Group-1)



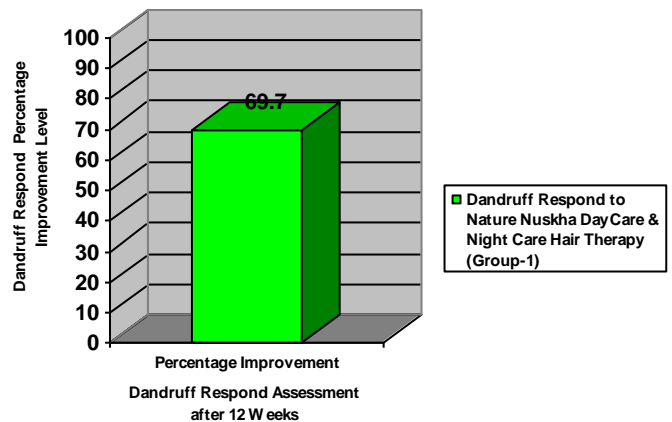
PRIMARY END POINT-DANDRUFF OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)					
Dandruff Measures	N volunteers	Mean	S.D.	Dandruff Assessment	
On inclusion	27	3.3	0.61	Improvement by	2.3
After 12 Weeks	27	1	0	% Improvement	69.70
	t-value	19.59205012			
	P-value (as compare to base line)	< 0.05 (S ^{***})			

S = Significant (<0.05) ; NS = Not Significant (>0.05)

Assessment of Dandruff Respond to Nature Nuskha Day Care & Night Care Hair Therapy (Group-1)



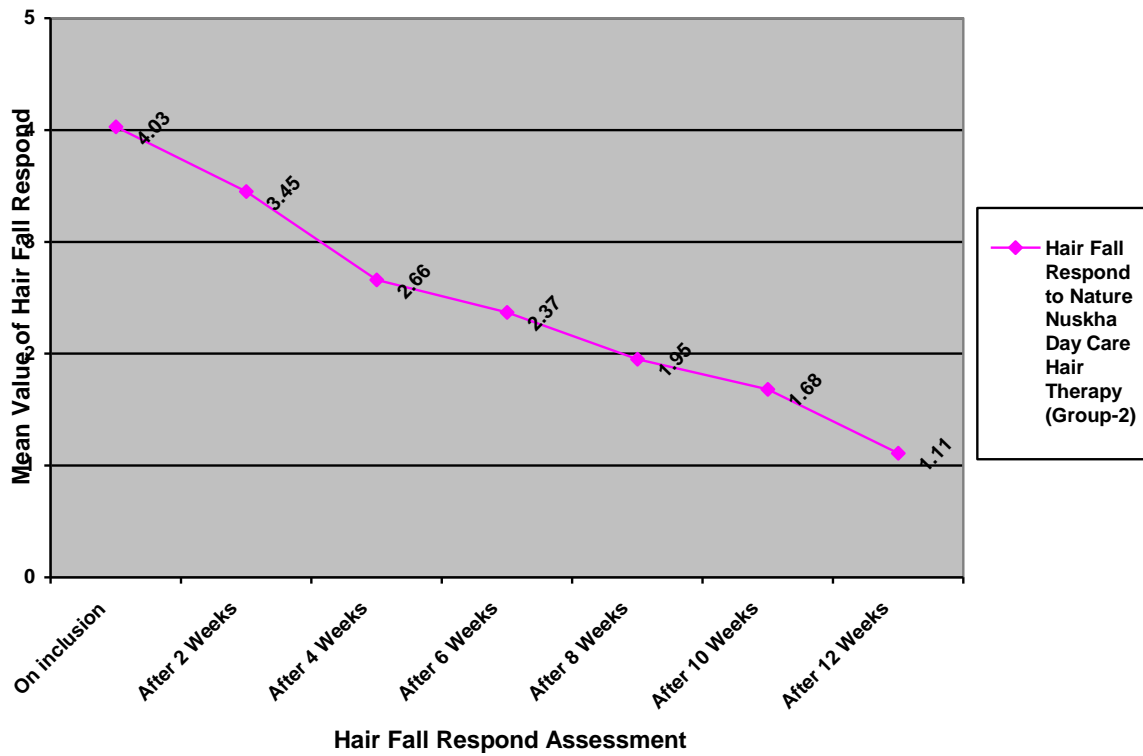
Assessment of Dandruff Respond to Nature Nuskha Day Care & Night Care Hair Therapy (Group-1)



PRIMARY END POINT-HAIR FALL ASSESSMENT OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)

Identification Number	1. Hair Fall						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10326	4	4	3	3	2	1	1
4/4489	4	4	3	3	2	2	1
4/4488	4	4	3	3	3	2	1
7/914	4	4	3	3	2	2	1
4/4495	4	4	3	3	2	2	1
4/4494	4	2	2	2	2	2	1
1/11752	4	3	2	1	1	1	1
1/11753	4	2	2	1	1	1	1
1/11747	4	4	3	3	2	2	1
4/4503	4	4	3	3	3	2	1
4/4593	4	3	3	2	1	1	1
1/11817	5	4	3	2	2	1	1
1/11005	4	3	2	2	2	2	1
4/4811	5	5	3	3	2	2	1
4/4812	5	5	3	3	2	2	1
4/4810	4	3	2	2	2	1	1
1/11111	5	4	3	2	2	2	1
1/11108	5	4	3	3	2	2	2
4/4894	5	5	3	3	3	2	1
4/4899	5	4	3	3	3	2	2
4/4467	3	2	2	1	1	1	1
4/5292	4	4	3	3	2	2	1
4/5330	4	3	3	2	2	2	1
4/5329	5	3	3	2	2	2	2
4/5320	3	3	2	2	2	2	1
4/5403	3	2	2	2	2	2	1
4/5349	4	4	3	3	2	2	2
4/5491	4	3	3	2	2	2	1
4/5490	3	3	2	2	2	2	1
4/5698	4	4	3	3	2	2	1
4/273	3	3	2	2	2	2	1
4/395	4	3	2	2	1	1	1
4/385	3	2	2	2	2	1	1
4/386	4	4	3	3	2	2	1
4/606	4	3	3	2	2	1	1
4/705	4	4	3	3	2	2	1
4/845	4	3	3	2	2	1	1
4/857	3	3	2	2	1	1	1
Mean Value	4.03	3.45	2.66	2.37	1.95	1.68	1.11
Std. Dev.	0.64	0.83	0.48	0.63	0.52	0.47	0.31

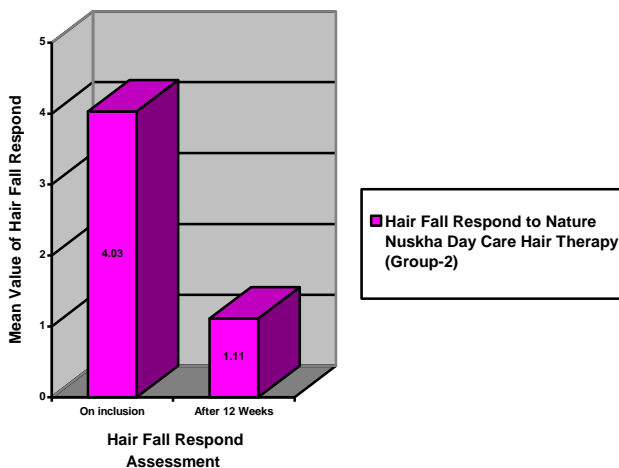
Assessment of Hair Fall Respond to Nature Nuskha Day Care Hair Therapy (Group-2)



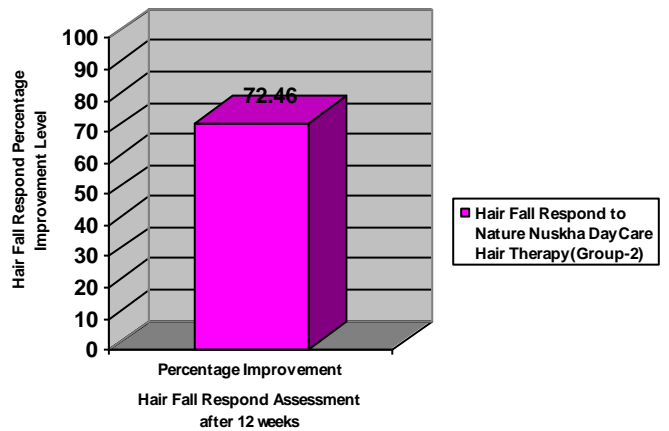
PRIMARY END POINT-HAIR FALL ASSESSMENT OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)						
Hair Fall Measures	N volunteers	Mean	S.D.	Hair Fall Assessment		
On inclusion	38	4.03	0.64	Improvement by	2.92	
After 12 Weeks	38	1.11	0.31	% Improvement	72.46	
	t-value	25.31209973				
	P-value (as compare to base line)	< 0.05 (S***)				

S = Significant (<0.05) ; NS = Not Significant (>0.05)

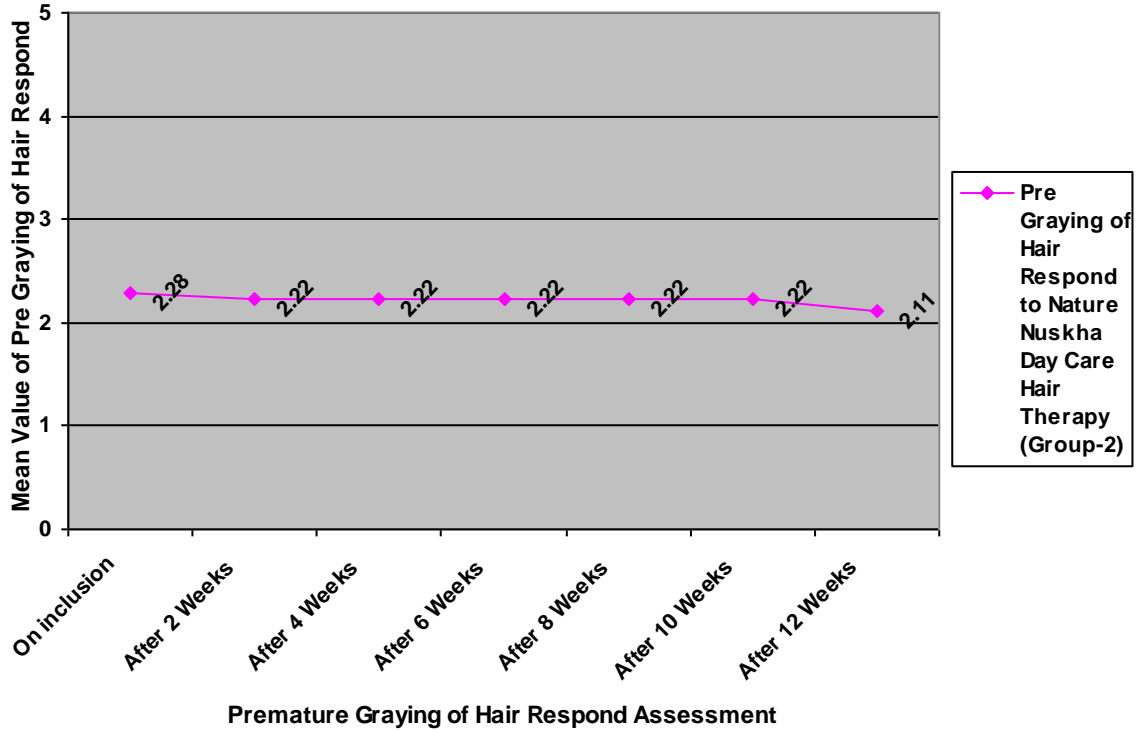
Assessment of Hair Fall Respond to Nature Nuskha Day Care Hair Therapy (Group-2)



Assessment of Hair Fall Respond to Nature Nuskha Day Care Hair Therapy (Group-2)



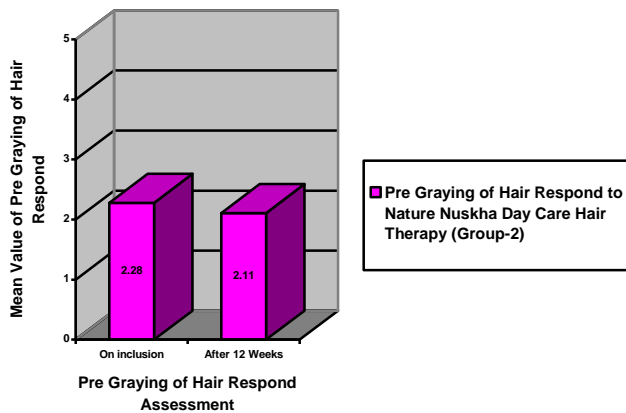
Assessment of Premature Graying of Hair Respond to Nature Nuskha Day Care Hair Therapy (Group-2)



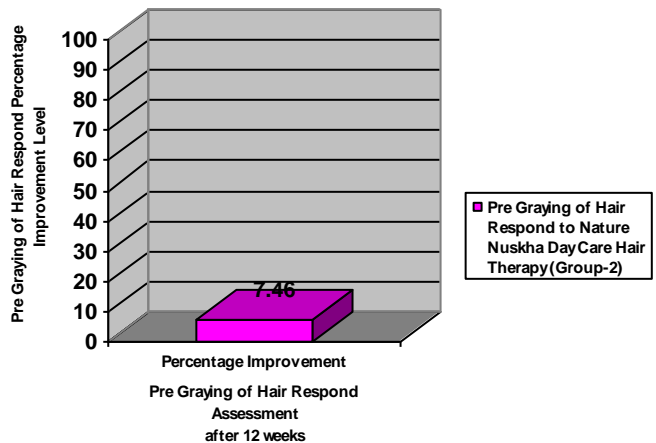
PRIMARY END POINT-PREATURE GRAYING OF HAIR ASSESSMENT OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)					
Premature Graying Hair Measures	N volunteers	Mean	S.D.	Premature Graying Hair of Assessment	
On inclusion	18	2.28	0.67	Improvement by	0.17
After 12 Weeks	18	2.11	0.58	% Improvement	7.46
	t-value	0.813893116			
	P-value (as compare to base line)	> 0.05 (NS)			

S = Significant (<0.05) ; NS = Not Significant (>0.05)

Assessment of Pre Graying of Hair Respond to Nature Nuskha Day Care Hair Therapy (Group-2)



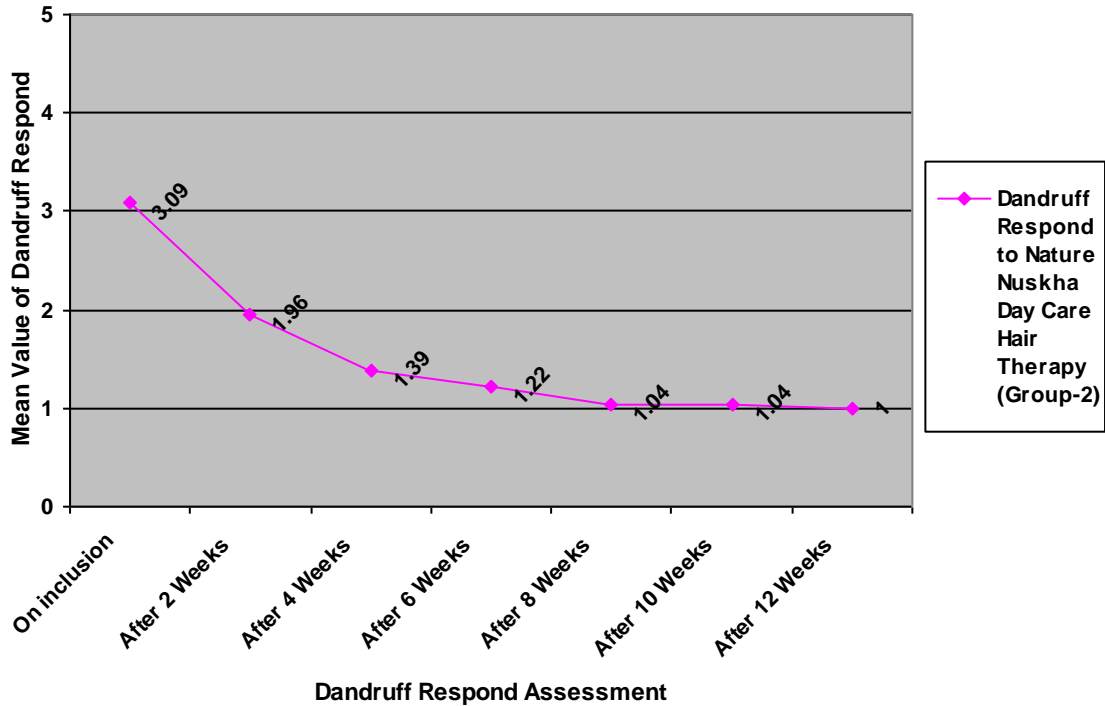
Assessment of Pre Graying of Hair Respond to Nature Nuskha Day Care Hair Therapy (Group-2)



PRIMARY END POINT-DANDRUFF ASSESSMENT OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)

Identification Number	3. Dandruff						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10326	4	2	1	1	1	1	1
4/4489	3	2	2	1	1	1	1
4/4488	NA	NA	NA	NA	NA	NA	NA
7/914	2	1	1	1	1	1	1
4/4495	3	2	1	1	1	1	1
4/4494	3	1	1	1	1	1	1
1/11752	3	2	1	1	1	1	1
1/11753	4	2	1	1	1	1	1
1/11747	NA	NA	NA	NA	NA	NA	NA
4/4503	3	1	1	1	1	1	1
4/4593	NA	NA	NA	NA	NA	NA	NA
1/11817	NA	NA	NA	NA	NA	NA	NA
1/11005	4	3	2	2	1	1	1
4/4811	4	3	1	1	1	1	1
4/4812	3	3	1	1	1	1	1
4/4810	NA	NA	NA	NA	NA	NA	NA
1/11111	3	2	2	2	2	2	1
1/11108	4	3	2	1	1	1	1
4/4894	3	2	1	1	1	1	1
4/4899	3	2	2	2	1	1	1
4/4467	3	1	1	1	1	1	1
4/5292	4	3	2	1	1	1	1
4/5330	NA	NA	NA	NA	NA	NA	NA
4/5329	3	2	2	1	1	1	1
4/5320	NA	NA	NA	NA	NA	NA	NA
4/5403	3	2	2	2	1	1	1
4/5349	3	3	2	2	1	1	1
4/5491	NA	NA	NA	NA	NA	NA	NA
4/5490	NA	NA	NA	NA	NA	NA	NA
4/5698	2	1	1	1	1	1	1
4/273	NA	NA	NA	NA	NA	NA	NA
4/395	NA	NA	NA	NA	NA	NA	NA
4/385	2	1	1	1	1	1	1
4/386	2	1	1	1	1	1	1
4/606	NA	NA	NA	NA	NA	NA	NA
4/705	NA	NA	NA	NA	NA	NA	NA
4/845	NA	NA	NA	NA	NA	NA	NA
4/857	NA	NA	NA	NA	NA	NA	NA
Mean Value	3.09	1.96	1.39	1.22	1.04	1.04	1.00
Std. Dev.	0.67	0.77	0.50	0.42	0.21	0.21	0.00

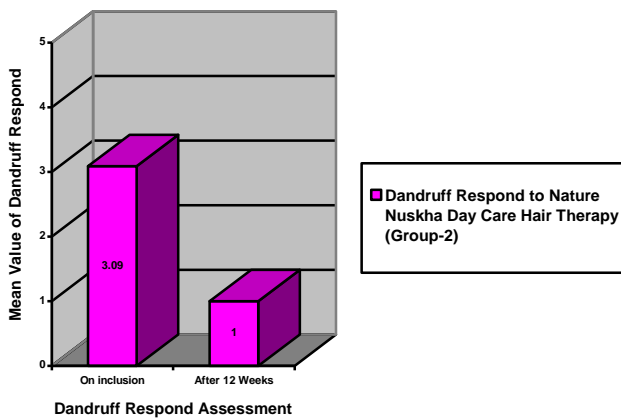
Assessment of Dandruff Respond to Nature Nuskha Day Care Hair Therapy (Group-2)



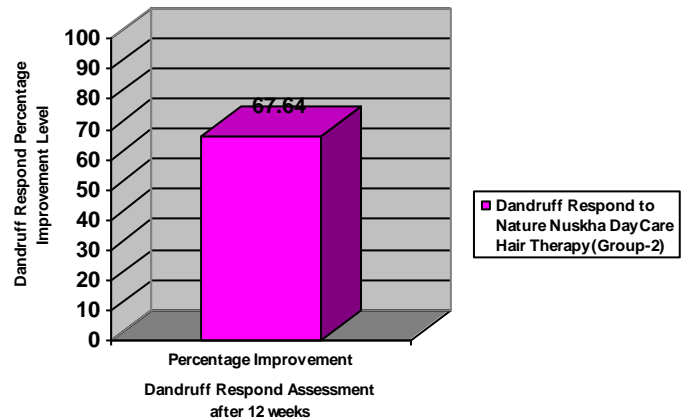
PRIMARY END POINT-DANDRUFF ASSESSMENT OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)						
Dandruff Measures	N volunteers	Mean	S.D.	Dandruff Assessment		
On inclusion	23	3.09	0.67	Improvement by	2.09	
After 12 Weeks	23	1	0	% Improvement	67.64	
	t-value	14.9613117				
	P-value (as compare to base line)	< 0.05 (S**)				

S = Significant (<0.05) ; NS = Not Significant (>0.05)

Assessment of Dandruff Respond to Nature Nuskha Day Care Hair Therapy (Group-2)



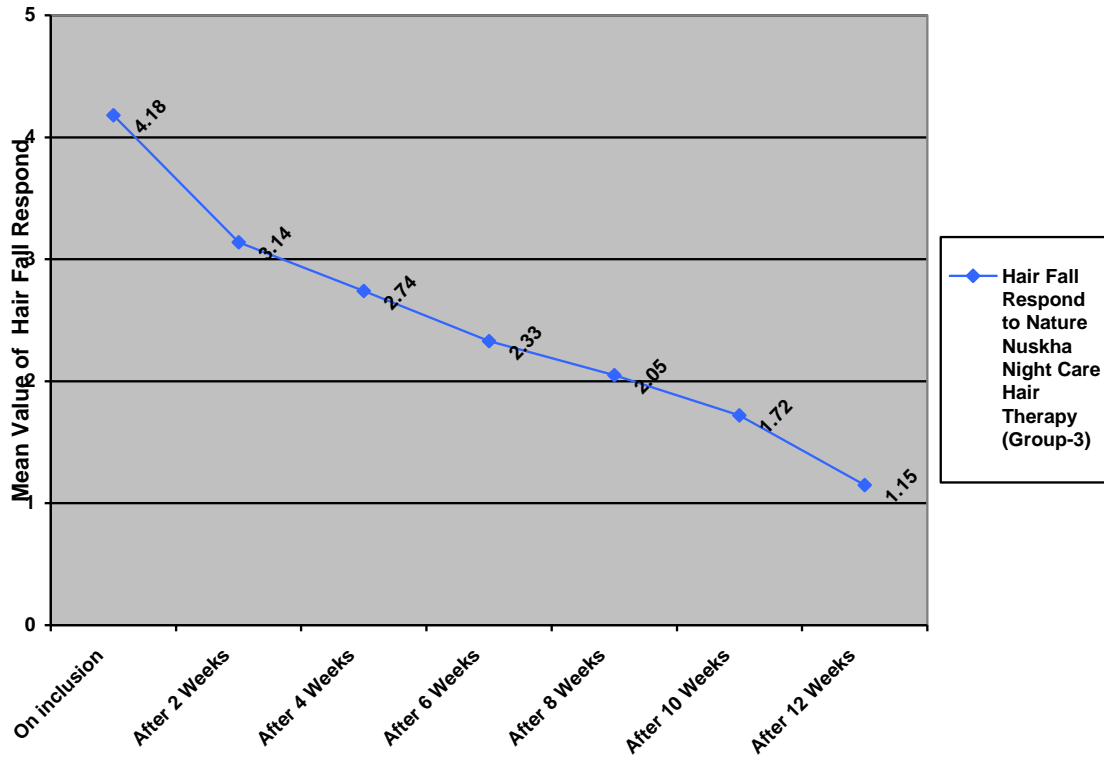
Assessment of Dandruff Respond to Nature Nuskha Day Care Hair Therapy (Group-2)



PRIMARY END POINT-HAIR FALL ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

Identification Number	1. Hair Fall						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10328	4	4	3	2	2	1	1
4/4349	4	4	3	3	2	2	1
7/913	4	3	3	2	2	1	1
4/4527	4	3	2	2	2	2	1
1/11745	4	4	3	3	3	2	1
1/11746	4	4	3	3	2	2	1
4/4588	4	3	3	2	2	1	1
1/11003	5	4	3	3	2	2	1
1/11007	4	3	2	2	2	1	1
1/11006	4	3	2	1	1	1	1
1/11109	5	4	3	3	2	2	1
4/4828	4	3	2	1	1	1	1
4/4827	5	4	3	2	2	1	1
4/5074	5	4	3	2	2	2	1
1/11203	3	3	3	2	2	2	1
4/5118	4	4	3	3	3	2	2
1/11206	5	3	2	2	2	2	1
4/4486	3	3	2	2	2	1	1
4/4487	3	3	3	2	2	2	1
4/5234	4	4	3	3	3	2	1
4/5214	5	3	3	3	3	2	2
4/5285	5	4	4	3	3	2	2
4/5288	4	3	3	3	2	2	2
4/5253	4	3	2	2	2	1	1
4/5342	5	3	2	2	2	2	1
4/5352	4	3	3	2	2	2	1
4/5415	5	4	3	2	2	2	1
4/543	5	4	3	3	2	2	1
4/5586	5	4	4	3	3	3	2
4/5516	4	4	3	3	3	2	1
4/5722	4	3	2	2	1	1	1
4/448	4	4	3	3	2	2	1
4/454	4	3	2	2	2	2	1
4/462	4	3	3	2	2	2	1
1/338	3	2	2	1	1	1	1
4/711	3	2	2	2	1	1	1
4/895	5	4	3	3	2	2	2
1/555	4	3	3	2	2	2	1
4/932	4	4	3	3	2	2	1
Mean Value	4.18	3.41	2.74	2.33	2.05	1.72	1.15
Std. Dev.	0.64	0.59	0.55	0.62	0.56	0.51	0.37

Assessment of Hair Fall Respond to Nature Nuskha Night Care Hair Therapy (Group-3)

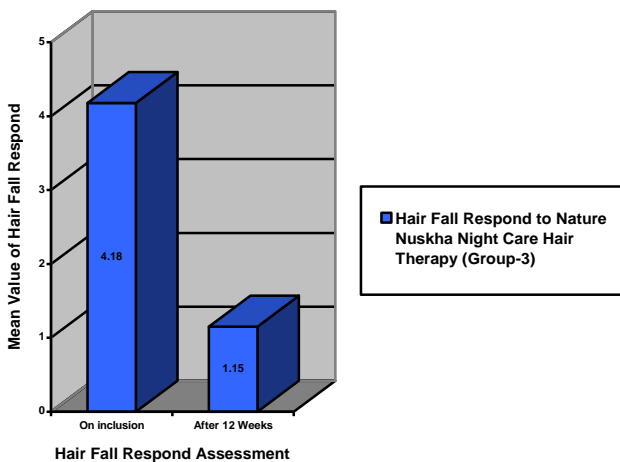


Hair Fall Respond Assessment

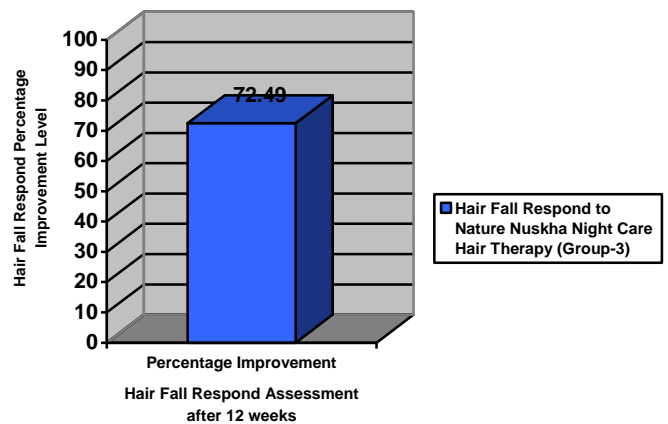
PRIMARY END POINT-HAIR FALL ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)					
Hair Fall Measures	N volunteers	Mean	S.D.	Hair Fall Assessment	
On inclusion	39	4.18	0.64	Improvement by	3.03
After 12 Weeks	39	1.15	0.37	% Improvement	72.49
	t-value	25.59645661			
	P-value (as compare to base line)	< 0.05 (S***)			

S = Significant (<0.05) ; NS = Not Significant (>0.05)

Assessment of Hair Fall Respond to Nature Nuskha Night Care Hair Therapy (Group-3)



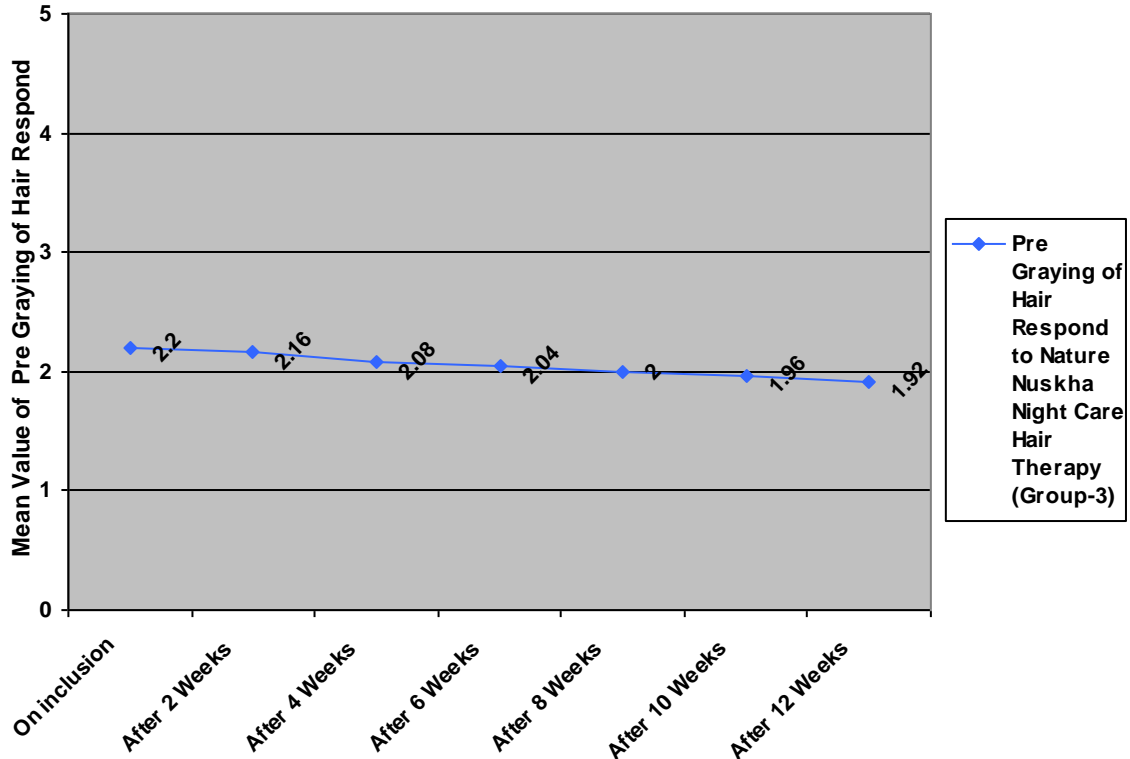
Assessment of Hair Fall Respond to Nature Nuskha Night Care Hair Therapy (Group-3)



PRIMARY END POINT-PREMATURE GRAYING OF HAIR ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

Identification Number	2. Premature Graying of Hair						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10328	NA	NA	NA	NA	NA	NA	NA
4/4349	NA	NA	NA	NA	NA	NA	NA
7/913	2	2	2	2	2	2	2
4/4527	NA	NA	NA	NA	NA	NA	NA
1/11745	3	3	3	3	3	3	2
1/11746	NA	NA	NA	NA	NA	NA	NA
4/4588	NA	NA	NA	NA	NA	NA	NA
1/11003	NA	NA	NA	NA	NA	NA	NA
1/11007	4	4	3	3	3	2	2
1/11006	4	3	2	1	1	1	1
1/11109	2	2	2	2	2	2	2
4/4828	2	2	2	2	2	2	2
4/4827	NA	NA	NA	NA	NA	NA	NA
4/5074	NA	NA	NA	NA	NA	NA	NA
1/11203	3	3	3	3	2	2	2
4/5118	2	2	2	2	2	2	2
1/11206	NA	NA	NA	NA	NA	NA	NA
4/4486	NA	NA	NA	NA	NA	NA	NA
4/4487	3	3	3	3	3	3	3
4/5234	2	2	2	2	2	2	2
4/5214	1	1	1	1	1	1	1
4/5285	2	2	2	2	2	2	2
4/5288	2	2	2	2	2	2	2
4/5253	2	2	2	2	2	2	2
4/5342	3	3	3	3	3	3	3
4/5352	2	2	2	2	2	2	2
4/5415	2	2	2	2	2	2	2
4/543	NA	NA	NA	NA	NA	NA	NA
4/5586	2	2	2	2	2	2	2
4/5516	1	1	1	1	1	1	1
4/5722	2	2	2	2	2	2	2
4/448	2	2	2	2	2	2	2
4/454	2	2	2	2	2	2	2
4/462	NA	NA	NA	NA	NA	NA	NA
1/338	NA	NA	NA	NA	NA	NA	NA
4/711	1	1	1	1	1	1	1
4/895	NA	NA	NA	NA	NA	NA	NA
1/555	1	1	1	1	1	1	1
4/932	3	3	3	3	3	3	3
Mean Value	2.20	2.16	2.08	2.04	2.00	1.96	1.92
Std. Dev.	0.82	0.75	0.64	0.68	0.65	0.61	0.57

Assessment of Premature Graying of Hair Respond to Nature Nuskha Night Care Hair Therapy (Group-3)

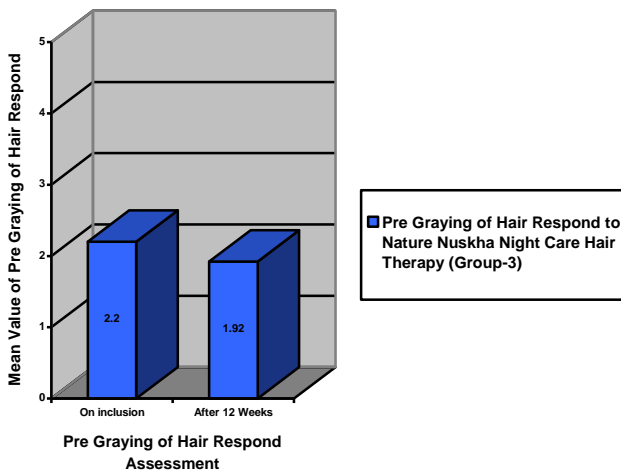


Premature Graying of Hair Respond Assessment

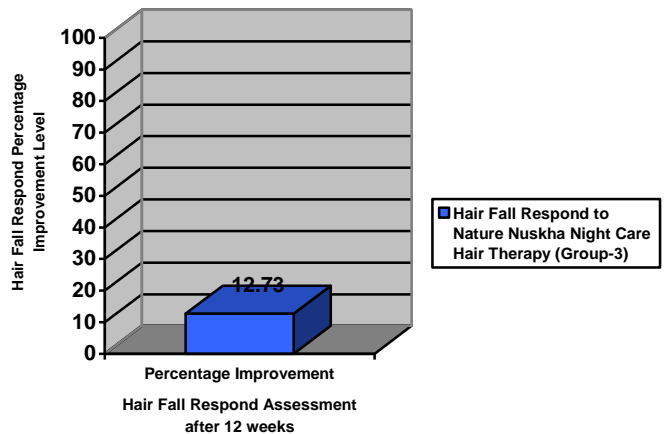
PRIMARY END POINT-PREMATURE GRAYING OF HAIR ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)					
Premature Graying Hair Measures	N volunteers	Mean	S.D.	Premature Graying Hair of Assessment	
On inclusion	25	2.2	0.82	Improvement by	0.28
After 12 Weeks	25	1.92	0.57	% Improvement	12.73
	t-value	1.401893836			
	P-value (as compare to base line)	> 0.05 (NS)			

S = Significant (<0.05) ; NS = Not Significant (>0.05)

Assessment of Pre Graying of Hair Respond to Nature Nuskha Night Care Hair Therapy (Group-3)



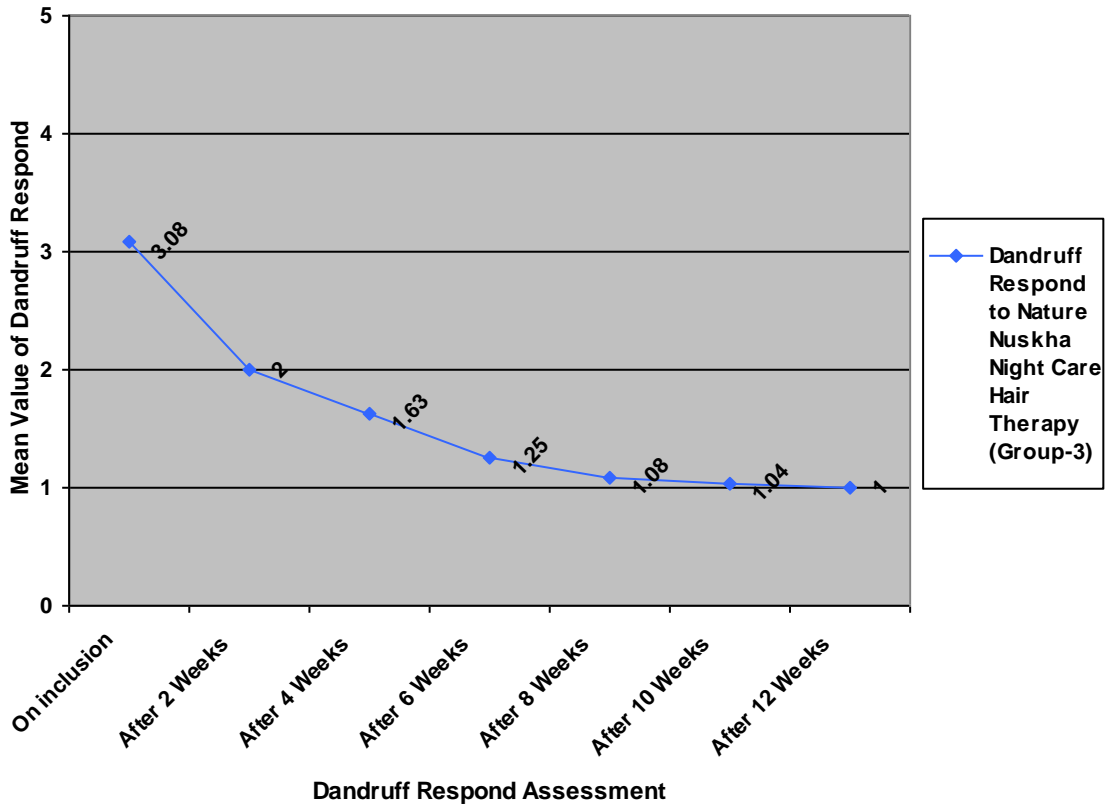
Assessment of Hair Fall Respond to Nature Nuskha Night Care Hair Therapy (Group-3)



PRIMARY END POINT-DANDRUFF ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

Identification Number	3. Dandruff						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10328	NA	NA	NA	NA	NA	NA	NA
4/4349	NA	NA	NA	NA	NA	NA	NA
7/913	3	2	2	1	1	1	1
4/4527	NA	NA	NA	NA	NA	NA	NA
1/11745	NA	NA	NA	NA	NA	NA	NA
1/11746	NA	NA	NA	NA	NA	NA	NA
4/4588	4	2	1	1	1	1	1
1/11003	3	3	3	2	2	1	1
1/11007	NA	NA	NA	NA	NA	NA	NA
1/11006	NA	NA	NA	NA	NA	NA	NA
1/11109	NA	NA	NA	NA	NA	NA	NA
4/4828	3	2	1	1	1	1	1
4/4827	2	1	1	1	1	1	1
4/5074	5	3	2	1	1	1	1
1/11203	NA	NA	NA	NA	NA	NA	NA
4/5118	3	2	2	2	2	2	1
1/11206	2	1	1	1	1	1	1
4/4486	NA	NA	NA	NA	NA	NA	NA
4/4487	NA	NA	NA	NA	NA	NA	NA
4/5234	3	2	1	1	1	1	1
4/5214	4	2	2	2	1	1	1
4/5285	3	2	2	2	1	1	1
4/5288	NA	NA	NA	NA	NA	NA	NA
4/5253	4	2	2	1	1	1	1
4/5342	NA	NA	NA	NA	NA	NA	NA
4/5352	2	1	1	1	1	1	1
4/5415	4	3	2	1	1	1	1
4/543	3	2	2	1	1	1	1
4/5586	4	3	3	2	1	1	1
4/5516	2	1	1	1	1	1	1
4/5722	2	1	1	1	1	1	1
4/448	NA	NA	NA	NA	NA	NA	NA
4/454	2	1	1	1	1	1	1
4/462	3	2	2	1	1	1	1
1/338	NA	NA	NA	NA	NA	NA	NA
4/711	4	3	2	2	1	1	1
4/895	4	3	2	1	1	1	1
1/555	2	2	1	1	1	1	1
4/932	3	2	1	1	1	1	1
Mean Value	3.08	2.00	1.63	1.25	1.08	1.04	1.00
Std. Dev.	0.88	0.72	0.65	0.44	0.28	0.20	0.00

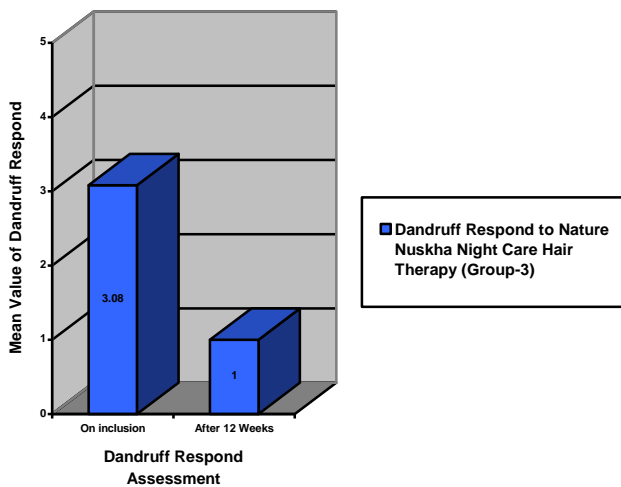
Assessment of Dandruff Respond to Nature Nuskha Night Care Hair Therapy (Group-3)



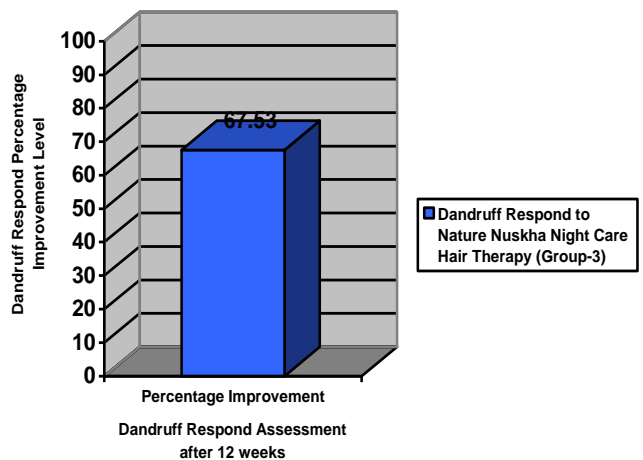
PRIMARY END POINT-DANDRUFF ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)					
Dandruff Measures	N volunteers	Mean	S.D.	Dandruff Assessment	
On inclusion	24	3.08	0.88	Improvement by	2.08
After 12 Weeks	24	1	0	% Improvement	67.53
	t-value	11.57940606			
	P-value (as compare to base line)	< 0.05 (S*)			

S = Significant (<0.05) ; NS = Not Significant (>0.05)

Assessment of Dandruff Respond to Nature Nuskha Night Care Hair Therapy (Group-3)



































Assessment of Dandruff Respond to Nature Nuskha Night Care Hair Therapy (Group-3)



*Secondary end Point: Visual Condition of Scalp with Hair Loss Assessment-***SECONDARY END POINT- ASSESSMENT OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)**

Identification Number	Visual Condition of Scalp with Hair Loss						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10374		NA		NA		NA	
1/10327		NA		NA		NA	
4/4334		NA		NA	NA		
4/4446				NA	NA		
4/4459			NA	NA	NA		
4/4460			NA	NA	NA		
4/4452		NA		NA	NA		
4/4461			NA	NA	NA		
4/4451		NA	NA	NA	NA		
7/915							
4/4518		NA			NA	NA	
4/4490				NA	NA	NA	
4/4822		NA	NA	NA	NA	NA	

4/4238		NA					
4/4830		NA		NA	NA	NA	
4/4330		NA	NA		NA	NA	
1/11117		NA	NA	NA	NA	NA	
4/5117		NA	NA		NA	NA	
4/5233		NA		NA	NA		
4/5221		NA	NA	NA	NA	NA	
4/5289			NA	NA	NA		
4/5326		NA	NA	NA	NA	NA	
4/5313				NA			
4/5318							
4/5330		NA		NA	NA	NA	
4/5343		NA		NA	NA	NA	
4/5342		NA		NA	NA	NA	



















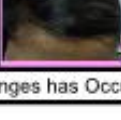

4/5341		NA		NA	NA	NA	
4/5523			NA	NA	NA	NA	
4/5694			NA	NA	NA	NA	
4/84		NA	NA	NA	NA	NA	
4/458			NA		NA		
4/497		NA		NA	NA	NA	
4/558						NA	
4/684		NA	NA	NA		NA	
4/770			NA	NA	NA	NA	
4/830		NA	NA	NA	NA	NA	
4/925				NA	NA	NA	
Visual Assessment Result : Mark Changes has Occurred in Visual Condition of Scalp with Hair Loss after 12 weeks							

SECONDARY END POINT- ASSESSMENT OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)		
N volunteers	Measures	Visual Condition of Scalp with Hair Loss
48	After 12 weeks	Mark Changes has Occurred

SECONDARY END POINT- ASSESSMENT OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)

Identification Number	Visual Condition of Scalp with Hair Loss						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10326		NA		NA		NA	
4/4489			NA	NA	NA	NA	
4/4488		NA		NA	NA	NA	
7/914		NA		NA	NA	NA	
4/4495			NA	NA	NA	NA	
4/4494			NA	NA	NA	NA	
1/11752			NA		NA	NA	
1/11753			NA	NA	NA		
1/11747		NA		NA	NA	NA	
4/4503		NA		NA	NA		
4/4593							
1/11817			NA		NA	NA	
1/11005		NA		NA	NA	NA	

4/4811				NA			
4/4812				NA	NA	NA	
4/4810				NA		NA	
1/11111		NA			NA	NA	
1/11108		NA	NA		NA		
4/4894				NA	NA		
4/4899		NA		NA	NA	NA	
4/4467			NA			NA	
4/5292		NA	NA	NA	NA	NA	
4/5330			NA			NA	
4/5329			NA			NA	
4/5320		NA					
4/5403			NA		NA	NA	
4/5349		NA	NA	NA	NA		

4/5491		NA	NA		NA	NA	
4/5490		NA	NA			NA	
4/5698		NA	NA	NA	NA	NA	
4/273		NA	NA	NA		NA	
4/395		NA	NA	NA	NA	NA	
4/385					NA		
4/386		NA	NA	NA	NA	NA	
4/606		NA	NA	NA	NA	NA	
4/705						NA	
4/845		NA	NA	NA	NA	NA	
4/857				NA	NA	NA	
Visual Assessment Result : Simple Changes has Occurred in Visual Condition of Scalp with Hair Loss after 12 weeks							

SECONDARY END POINT- ASSESSMENT OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)

N volunteers	Measures	Visual Condition of Scalp with Hair Loss
48	After 12 weeks	Simple Changes has Occurred

SECONDARY END POINT- ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

Identification Number	Visual Condition of Scalp with Hair Loss						
	On inclusion	After 2nd Week	After 4th Week	After 6th Week	After 8th Week	After 10th Week	After 12th Week
1/10328		NA		NA		NA	
4/4349		NA		NA		NA	
7/913			NA	NA	NA	NA	
4/4527		NA		NA	NA	NA	
1/11745		NA		NA	NA	NA	
1/11746			NA	NA	NA	NA	
4/4588				NA		NA	
1/11003		NA		NA	NA	NA	
1/11007		NA		NA	NA		
1/11006			NA		NA		
1/11109		NA		NA	NA	NA	
4/4828			NA		NA	NA	
4/4827					NA	NA	

4/5074		NA	NA		NA	NA	
1/11203		NA	NA			NA	
4/5118		NA	NA	NA	NA	NA	
1/11206			NA			NA	
4/4486		NA	NA	NA	NA		
4/4487		NA	NA	NA	NA	NA	
4/5234		NA		NA		NA	
4/5214				NA	NA	NA	
4/5285		NA	NA	NA		NA	
4/5288			NA	NA	NA	NA	
4/5253				NA	NA	NA	
4/5342					NA		
4/5352			NA	NA	NA	NA	
4/5415		NA			NA		

4/543		NA		NA	NA	NA	
4/5586		NA	NA	NA		NA	
4/5516		NA		NA	NA	NA	
4/5722				NA			
4/448		NA	NA	NA	NA	NA	
4/454				NA		NA	
4/462		NA	NA	NA	NA	NA	
1/338		NA	NA	NA	NA	NA	
4/711		NA		NA	NA	NA	
4/895			NA	NA	NA	NA	
1/555		NA		NA	NA	NA	
4/932		NA	NA	NA	NA	NA	

Visual Assessment Result : Moderate Changes has Occurred in Visual Condition of Scalp with Hair Loss after 12 weeks

SECONDARY END POINT- ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

N volunteers	Measures	Visual Condition of Scalp with Hair Loss
49	After 12 weeks	Moderate Changes has Occurred

Safety Assessment:**SAFETY ASSESSMENT OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)**

SAFETY ASSESSMENT OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)		
Safety Parameters	Mean value (Std. Dev.)	Mean value (Std. Dev.)
	On inclusion	After 12 weeks
N volunteers	48	48
Hb% (gm/dl)	11.2 (1.2)	11.5 (1.1)
ESR (mm 1 st hr.)	12.2 (6.3)	12.0 (5.5)
Blood Sugar- R (mg/dl)	102.5 (16.1)	101.2 (11.3)
Blood Urea (mg/dl)	28.9 (4.8)	30.0 (3.5)
S. Bilirubin (mg/dl)	0.7 (0.2)	0.6 (0.1)
URINE R/M	NAD	NAD

SAFETY ASSESSMENT OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)

SAFETY ASSESSMENT OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)		
Safety Parameters	Mean value (Std. Dev.)	Mean value (Std. Dev.)
	On inclusion	After 12 weeks
N volunteers	48	48
Hb% (gm/dl)	11.2 (0.9)	11.3 (1.0)
ESR (mm 1 st hr.)	11.6 (5.0)	10.8 (4.1)
Blood Sugar- R (mg/dl)	102.9 (14.6)	100.9 (11.7)
Blood Urea (mg/dl)	27.8 (5.5)	29.0 (3.8)
S. Bilirubin (mg/dl)	0.7 (0.2)	0.6 (0.1)
URINE R/M	NAD	NAD

SAFETY ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

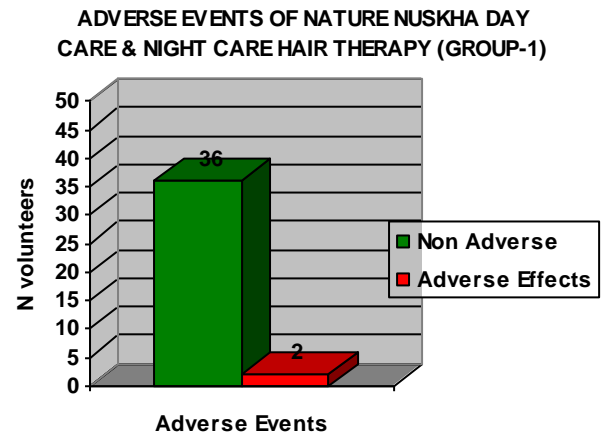
SAFETY ASSESSMENT OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)		
Safety Parameters	Mean value (Std. Dev.)	Mean value (Std. Dev.)
	On inclusion	After 12 weeks
N volunteers	49	49
Hb% (gm/dl)	11.5 (0.9)	11.8 (0.7)
ESR (mm 1 st hr.)	11.1 (5.5)	10.1 (3.5)
Blood Sugar- R (mg/dl)	99.8 (13.6)	104.7 (13.3)
Blood Urea (mg/dl)	28.2 (5.0)	30.2 (4.1)
S. Bilirubin (mg/dl)	0.7 (0.1)	0.7 (0.1)
URINE R/M	NAD	NAD

Safety Events:

On the basis of statistical analysis of Safety Parameters there is no change in Blood & Urine values after 12 weeks duration of clinical trial. **Therefore Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit is safe to used for long time.**

Adverse Events:**ADVERSE EVENTS OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)**

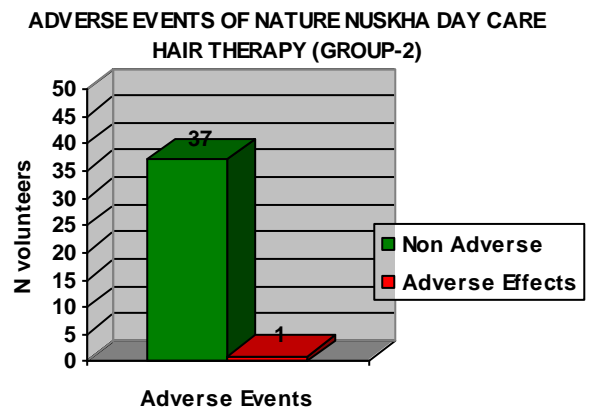
ADVERSE EVENTS OF NATURE NUSKHA DAY CARE AND NIGHT CARE HAIR THERAPY (GROUP-1)	
N volunteers	38
Non Adverse	36
Adverse Affects	2



Non Adverse	36
Adverse Effects	2

ADVERSE EVENTS OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)

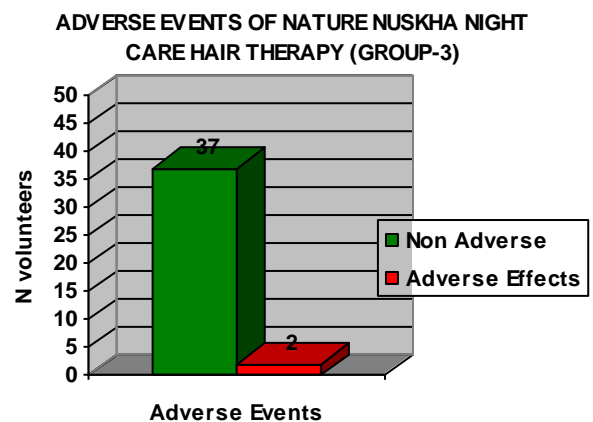
ADVERSE EVENTS OF NATURE NUSKHA DAY CARE HAIR THERAPY (GROUP-2)	
N volunteers	38
Non Adverse	37
Adverse Affects	1



Non Adverse	37
Adverse Effects	1

ADVERSE EVENTS OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)

ADVERSE EVENTS OF NATURE NUSKHA NIGHT CARE HAIR THERAPY (GROUP-3)	
N volunteers	39
Non Adverse	37
Adverse Affects	2



Non Adverse	37
Adverse Effects	2

Adverse Events:

No serious adverse effect was either observed or reported during the entire clinical trial.

Two out of 38 subjects who completed the study in group-1 subjected Combination Scalp Treatment with Herbal Hair Tonic Nature Nuskha Day Therapy and Night Therapy Kit (G-1) reported boils on forehead, which lasted for about a week and did not require any treatment and subsided of its own.

One out of 38 subjects who completed the study in group-2 subjected Single Scalp Treatment study with Herbal Hair Tonic Nature Nuskha Day Therapy (G-2) reported boils on forehead, which lasted for about a week and did not require any treatment and subsided of its own

Two subjects out of 39 who completed the study in group-3 subjected Single Scalp Treatment study with Herbal Hair Tonic Nature Nuskha Night Therapy (G-3) reported boils on forehead, which lasted for about a week and did not require any treatment and subsided of its own.

Conclusion:

All the three group trial of Herbal Hair Tonic Nature Nuskha Day Care and Night Care Hair Therapy were well tolerated. A few subjects complained of mild boils on forehead which lasted for about a week and which subsided of its own without requiring any medication.

Response of group trial of Herbal Hair Tonic Nature Nuskha Day Care and Night Care Hair Therapy in Improving in Hair Fall, Premature Graying of Hair and Dandruff from the base level of Scalp Condition by tested therapy in subjects having Various Scalp Condition after 12 weeks has been summarized in the following table:

Nature Nuskha Hair Therapy Trial Group	Hair Fall On Inclusion (Average)	Hair Fall After 12 Weeks (Average)	Percentage Improvement
Nature Nuskha Day Care & Night Care Hair Therapy Group-1	4.26	1.16	72.77
Nature Nuskha Day Care Hair Therapy Group-2	4.03	1.11	72.46
Nature Nuskha Night Care Hair Therapy Group-3	4.18	1.15	72.49

Nature Nuskha Hair Therapy Trial Group	Dandruff On Inclusion (Average)	Dandruff After 12 Weeks (Average)	Percentage Improvement
Nature Nuskha Day Care & Night Care Hair Therapy Group-1	3.30	1.00	69.70
Nature Nuskha Day Care Hair Therapy Group-2	3.09	1.00	67.64
Nature Nuskha Night Care Hair Therapy Group-3	3.08	1.00	67.53

So it can be concluded that Herbal Hair Tonic Nature Nuskha Day Care and Night Care Hair Therapy has been well tolerated after 12 weeks of administration and is able to reduced Hair Fall & Dandruff in subjects suffering from Various Scalp Condition and may be taken up for said clinical therapy.

ETHICAL CONSIDERATION

Basic Principles:

The research was carried out in accordance with the Basic Principles defined in the ICH' Guidance for Good Clinical Practice' and the principles enunciated in the Declaration of Helsinki which states that "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

Independent Ethics Committee (IEC):

This protocol and the corresponding informed consent forms (ICFs including both English and Hindi) used to obtain informed consent of study objects were reviewed by IEC and the study subjects were not dosed till the IEC approved the protocol and the ICF, as submitted or with modifications. The committee is constituted and operates in accordance with the principles and requirements described in the US code of Federal Regulations (21CFR Part 56)/Schedule Y,2005 and ICMR guidelines,2000(Ethical guidelines for biomedical research on human subjects)

Informed Consent:

The clinical investigator and his designate informed the subjects before the initiation of study through an oral presentation regarding the purpose, procedures to be carried out, potential hazards and the rights of subjects. Subjects were made to understand and sign a consent form summarizing the discussion prior to admission for the study in Period .A copy of the informed consent statement is being provided in the final report.

Drop-out/Withdrawal of Subjects from the Study:

The subjects were informed that they would be free to drop out from the study at any time without stating any reason. The investigator was authorized to drop any subject from the study for any of the following reasons:

- 1) The subject suffers from significant inter-current illness or undergoes surgery during the course of the study.
- 2) The subject failed to comply with the requirements of the protocol. This includes pre-study directions regarding drug use or if the subject is uncooperative during the study.

33 volunteer dropped from the study did not come for the follow up as advised without giving any reason.

Medical Treatment for Injury:

There was no study related injury reported and hence no treatment required.

BENEFITS:

Since the drug is herbal in nature and the various herbal ingredients used in the formulation have been used in the treatment of various scalp condition hair related ailments in Ayurveda for a long

time, the probability of its being safe for long term use are high. The majority of the presently used drugs to treat Hair Fall, Premature Graying of Hair & Dandruff are associated with a number of side effects. So if this herbal drug is found to be effective in the long term, it will be major breakthrough in the treatment of this disease.

NEW FINDINGS:

Any new and important information discovered during the study may influence the treatment modalities available for the management of various scalps condition viz. Hair Fall, Premature Graying of Hair & Dandruff.

ALTERNATIVE TREATMENT:

Since this study is for research only and a number of drugs are available for the treatment of various scalps condition viz. Hair Fall, Premature Graying of Hair & Dandruff.

FINANCIAL COMPENSATION:

As no adverse side effect was reported, no compensation on drug related adverse effect treatment was required.

DATA MANAGEMENT

Study Documentation:

All data generated during the conduct of the study was directly entered in the raw data recording forms. All raw data and the transcribed data forms were completed by the study personnel assisting the study and checked wherever applicable for the completeness and the logistics by the clinical investigator or the designated study coordinator for the data. The clinical investigator and the coordinator supervised compilation of data until ready for archiving.

Supplementary Documentation:

The final report includes a sample of the protocol, informed consent form along with translated copies, a copy of IEC approval, randomization schedule, and the clinical raw data consisting of medical history, physical examination and the clinical laboratory case records, adverse reaction documentation and the actual time of dosing

Quality Assurance Audits:

The raw data generated during the course of the study, including the clinical and analytical operations and the final reports is liable for inspection and quality audit for confirmation according to the approved protocol and all the governing SOPs by an auditor from Quality Assurance unit of PEPL.

Accessibility:

Accessibility of the raw data will be limited to IEC, sponsor and the regulatory agencies for scheduled monitoring inspection and audits.

Confidentiality of Data:

The data identifying each study subjects by name will be kept confidential and will be accessible to the study personnel, Quality Assurance Auditor during audits and if necessary, to the IEC and various regulatory agencies.

Achieves:

A representative sample of the drug supplies used in the study will be retained at PEPL, clinical section. All data generated in connection with this study, together with the original copy of this protocol and the final report will be archived at PEPL.

Publication Policy:

Publication of the results of the study, whether in whole or part, shall be within the sole and absolute discretion of the sponsor i.e. Promed Exports Pvt Limited. In the publication subject's identity will not be revealed.

Deviations:

There was no deviation in the protocol.

Sponsor's Study Monitor:

Dr. Arvind Macchar, Head, IQGEN-X Pharma Pvt. Ltd. Navi Mumbai. INDIA was sponsor's monitor of the study.

Termination of the Study:

As no adverse drug related event was not reported, the study completed its schedule.

Study Monitoring and Supervision:

The study was monitored under the supervision of Dr Santosh Kumar Principal Investigator, and by Dr Atul Kumar, Co-investigator of the study.

A representative sample of the drug used in the study is being retained at PEPL. All data generated in connection with this study, together with the original copy of this protocol and the final report will be archived at PEPL.

Investigational Product Management:

- a. The following information was provided on the label.
Name of the product: **Nature Nuskha Day Care – Herbal Extract** Content-90 ml
Product code No.:IQ025(India) B.N.:----- (005)07
Name of the product: **Nature Nuskha Night Care – Oil Extract** Content-90 ml
Product code No.: IQ024(India) B.N.:----- (005)06
Mfg.Date -----April 2018 Exp.Date -----May 2020
SAMPLE FOR RESEARCH TRIALS ONLY
Mfd.By: IQGEN-X Pharma Pvt. Ltd. Navi Mumbai. INDIA
- b. Dose: 2-3 ml applied on the scalp twice, Nature Nuskha Day Therapy in the Morning after bath and Night Therapy at Night before sleep respectively.

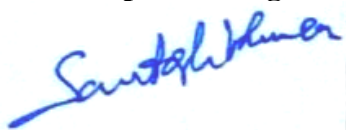
- c. The investigator was supplied with the coded samples of drugs having the same number as that of the patient.
- d. All odd randomized numbers received the drug and the even number received.
- e. Storage conditions for study substances: Store at a temperature up to 25 C away from heat and light. Do not refrigerate.
- f. Investigational Product Accountability: (i) Vials containing Drug were assigned numbers according to the randomized table and a record of all such randomized vials is kept at GEN-X Pharma Pvt. Ltd. Navi Mumbai. INDIA by Dr. Arvind Macchar.(ii) depending upon the requirement a lot of 300 vials be sent. (iii) It was received by the Investigator and entered in the register/stock book (iv) On the instructions of the ophthalmologist/investigator the patient were issued the vials and its number recorded on the CRF. (v) In the register the Patients name /the code number were recorded. (v) Every time the patient visits he was given the same number of vial having the same number and the earlier vials were recovered from him. (vi) The vials will be stored at a temperature up to 25 C away from heat and light in the cupboard.
- g. After the completion of the study all the unused vials were taken back from the investigation centre and brought back at The GEN-X Pharma Pvt. Ltd. Navi Mumbai. INDIA and their random and total number will be recorded by Dr Santosh Kumar. The vials were opened and contents thrown and the plastic containers were destroyed by cutting in the presence of Dr Santosh Kumar and entered in the register and signed by him.

Data analysis:

At least 30 patients are required in one group to provide statistically significant interpretation so the number of patients in each group i.e. treatment has been kept at 30.

Undertaking by the investigator:**Appendices:**

Provide a study synopsis, copies of informed documents (patient information sheet, informed consent form etc.); CRF and other data collection forms; a summary of relevant pre-clinical safety information and any other document referenced in the clinical protocol.

Principal Investigators:**(Dr. Santosh Kumar)**

M.D. (Ayurveda)

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S.R.M. State Ayurvedic Medical College
& Hospital, Bareilly (U.P.) INDIA

Co-Investigator:**(Dr. Atul Kumar)**

M.D. (Ayurveda)

Lecturer, Ayurvedic Pharmaceutics Department,
S.R.M. State Ayurvedic Medical College
& Hospital, Bareilly (U.P.) INDIA