CLINICAL TRIAL REPORT OF CHOLESTOBLAST CAPSULE

Manufactured by:-

Ruchi Soya Industries Limited, Khasra No. 92-93, Vill. Makkhanpur, Bhagwanpur, Roorkee, Haridwar, (U.K.)

Formulated & Marketed / Funding By:-

Trigya Health Products Private Limited, E-375, Ist Floor, Greater Kailash -II, Delhi-110048

Place of study: - Prankamiya Ayurveda, Dr. Sharma's Hospital, 95/1 Rajpura Gurmandi , Delhi -110007

Packing Details: - Packed 60 Capsules in a Bottle

Best Before: - 36 Months from before the date of Mfg.

Formulation: - Approved By Directorate of Ayurveda, Dehradun (Uttarakhand)

Mfg. Lic. No.:- UK AY- 216 / 2010

Composition:

Each capsule Contains

S. NO.	Common name	Botanical name	Part used	Sastriya prayog	Qty in mg	Ref book
1	Turmeric	Curcuma longa extract	Rhizome	Raktashodhak, Vishghan, Shoth Har	450	BPN: 111
2	Black Pepper 5% Pipperine	Piper nigrum extract	Fruit	Agnimand, Rochak Har	10	BPN: 17
3	Turmeric (95%Curcumin)	Curcuma longa extract	Rhizome	Raktashodhak, Vishghan, Shoth Har, Yakrit Vikar Har	30	BPN: 111

Dosages form

- Oral

Dosage

- Adult: 1 to 2 capsule twice a day or as directed by physician.

Vehicle

- With Luke warm water.

Indication

- Blood purifier (Rakta Shodhak), Anti allergic (Vishghan), Healthy cholestrol

Date of Starting

- 09/11/2016

Date of Completion - 11/01/2017

- 1. Dr. Harsh Gupta

Trial Done By

B.A.M.S, M.D (Ayu.)

PRANKAMIYA AYURVEDA (Committee Fanchkarma & Kaharautra

> Directo Vd. Harsh Gupta, (494.)

2. Dr. Shivani Kapil

B.A.M.S, M.S (Ayu.)

Number of Patient -

INTRODUCTION: Directions for Use: Take 1 Capsule twice a day or as directed by physician.

Study design

This study was a prospective, open, clinical trial, conducted at the clinic from 09/11/2016 to 11/01/2017

Inclusion criteria

A total of 40 patients, of both sexes, aged from 40 to 60 years, with chronic disease, atherosclerosis due to cholesterol High blood pressure, LDL and HDL related disorder and who were willing to give informed consent were included in the study.

Exclusion criteria

Persons with known hypersensitivity to any of the ingredients of the formulation, any facial wound or abrasion, and who were not willing to give informed consent were excluded from the study.

Study procedure

A baseline history was obtained in order to determine the patient's eligibility for enrolment in the trial. The baseline assessment included personal data, a description of symptoms and details of past medical history (family history, history of possible exacerbating factor/s, etc.).

All the patients were advised to take the "PRESERVA CHOLESTOBLAST CAPSULE", twice -a-day for a period of 12 weeks.

The subjective improvement evaluation was done by a predefined global grading system, which included following gradations: "No improvement", "fair improvement", "remarkable improvement", "very good improvement" and "excellent improvement".

Follow-up and monitoring

All the patients were followed up for a period of 12 weeks, and at each weekly follow-up visit, the safety, and the improvement in cholesterol management and chronic disease was evaluated. At the end of the 12 week, the overall performance of the "PRESERVA CHOLESTOBLAST CAPSULE" product was evaluated.

Primary and secondary end points

The predefined primary end point was improved blood circulation and the predefined secondary safety endpoints (for short- and long-term) were assessed by the incidence of adverse events and patient compliance to the therapy

Adverse events

All the adverse events either reported or observed by the patients were recorded with information about the severity, date of onset, duration and action taken regarding the study drug.

Relation of adverse events to the study medication were predefined as

"Unrelated" (a reaction that does not follow a reasonable temporal sequence from the time of administration of the drug),

"Possible" (follows a known response pattern to the suspected drug, but could have been produced by the patient's clinical state or other modes of therapy administered to the patient)

"Probable" (follows a known response pattern to the suspected drug that could not be reasonably explained by the known characteristics of the patient's clinical state).

RESULTS:- A total of 40 patients were enrolled in the study. There was significant improvement in the "PRESERVA CHOLESTOBLAST CAPSULE" after 12 weeks application, and the improvement trend continued, till the end of the study period.

Vd. Harson — pla, MD (Avu.)

Out of 40 subjects, 25 had "Remarkable" improvement,

9 had "Very Good" improvement,

6 had "Excellent" improvement in the cholesterol related disorder.

There were no clinically significant adverse reactions, either reported or observed, during the entire study period and the overall compliance to "PRESERVA CHOLESTOBLAST CAPSULE" was excellent.

The principle constituents of Turmeric and Black pepper (Piper nigrum)

Turmeric and Black pepper (Piper nigrum) have become the chief weapon in the war on cholesteroi related disorder.

The results of some new studies are promising, indicating that Turmeric and Black papper (Piper nigrum) can increase the blood circulation, High and low blood pressure and blood clots and have antioxidants property that are known to help protect the toxins, and help to regenerate heart cells

The excellent effects of "PRESERVA CHOLESTOBLAST CAPSULE" might have been due to the synergistic antioxidant, heart tonic, and properties of the ingredients, which also have excellent safety profile.

CONCLUSION:-

"PRESERVA CHOLESTOBLAST CAPSULE"

45 % decrease in the chronic cardiac disease

35% control in blood pressure

18 % decrease in atherosclerosis

This study observed a significant improvement in which also have excellent safety profile. Therefore, it may be concluded that "PRESERVA CHOLESTOBLAST CAPSULE" is effective and safe for usage, in the management of cholesterol, blood clots etc

The chronic disease and blood circulation related disorder are causes population and often poorly understood and managed.

PRE-DISPOSING FACTORS

i. Hereditary

ii. Constipation

iii. Occupation

iv. Eating

JUSTIFICATION OF HERBAL THERAPY

A total of 40 patients, of both sexes, aged from 40 to 60 years, Cardiac issues and related disorder, and who were willing to give informed consent in the study.

STATICAL DATA: (According to Sex)

Sex	No. of Patient
Male	18
Female	22 PRANKAMIYA AYUP TOA (Center for Panchkarma & Kanassutra ther.
	Male

Director Vd. Harsh Gupta, MD (مريد)

STATICAL DATA: (According to Age)

S. No.	Age	No. of Patient	
1-	Between 40 to 45	5	
2-	Between 46 to 50	17	
3-	Between 51 to 55	12	
4-	Between 56 to 60	6	

STATICAL DATA: (According to Diet)

Diet Habit	No. of Patient	
Vegetarian	18	
Non-Vegetarian	22	
	Vegetarian	Vegetarian 18

OBSESVATION & CRITERIA

Criteria of Heart related and cholesterol related disorder were the following:

- 1- Decrease cell fatigue in chronic diseases
- 2- Decrease Atherosclerosis
- 3- Relief from constipation
- 4- Control of secondary infection

Patients were also interrogated for any side effects occurring during the period of the trial.

1. Dr. Harsh Gupta B.A.M.S, M.D (Ayu.)

PRANKAMIYA AYURV (Genter for Panchkarma & Kshare & heraes)

Vd. Harsh Gupta, and Garal