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ORIGINAL ARTICLE

OPEN LABEL SINGLE CENTRIC CLINICAL EXPLORATORY OF EFFICACY STUDY ON TOTAL ANTIOXIDANT CAPSULE, AN AYURVEDIC PROPRIETARY FORMULATION

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ABSTRACT

Introduction: Oxidative stress plays a significant role in the development of various health conditions, including anemia (Paanduroga), muscle wasting (Dhathukshaya), general weakness (Dourbalya), and nervous debility. Chronic exposure to environmental toxins, poor diet, stress, and lifestyle disorders contributes to increased free radical production, leading to cell damage, inflammation, and weakened immune function. Conventional treatments focus on synthetic antioxidants and dietary modifications, but these may not always be effective and could pose long-term side effects. Ayurvedic medicine offers a natural and holistic approach to combating oxidative stress, supporting tissue regeneration, and enhancing immunity. This study clinically validates Total Antioxidant Capsule, a proprietary Ayurvedic formulation, for its efficacy in improving antioxidant levels, reducing inflammation, and enhancing immune function. The primary objective of this Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial was to evaluate the efficacy and safety of Total Antioxidant Capsule in relieving oxidative stress-induced conditions, improving energy levels, and enhancing immune function. **Methods:** A total of 20 patients with oxidative stress-related symptoms were enrolled following ethical clearance. Patients were administered 1-2 capsules twice daily with lukewarm water for 30 days. Clinical investigations and laboratory assessments were conducted on Day 1 (Baseline) and Day 30 (End of Trial) by qualified AYUSH practitioners. Parameters such as fatigue, muscle strength, inflammation markers, hemoglobin levels, and immune response were monitored throughout the study. **Results:** At the end of 30 days, 80% (16 patients) exhibited very good improvement, 15% (3 patients) showed moderate improvement, and 5% (1 patient) had mild improvement. The formulation significantly reduced inflammation, enhanced antioxidant levels, and improved overall vitality. No adverse effects were reported. **Conclusion:** The study confirms that Total Antioxidant Capsule is an effective Ayurvedic intervention for reducing oxidative stress, improving energy levels, and strengthening immune function. The formulation demonstrated significant improvements in overall health and vitality, making it a promising natural alternative. Further large-scale trials are recommended for broader validation.

Keywords: Oxidative stress, Anemia, Muscle wasting, Nervous debility

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INTRODUCTION

Oxidative stress is a key factor contributing to chronic diseases, aging, and metabolic disorders. It occurs when there is an imbalance between free radicals (reactive oxygen species) and the body's ability to detoxify them using antioxidants[1]. Free radicals damage cells, proteins, and DNA, leading to conditions such as anemia (Paanduroga), muscle wasting (Dhathukshaya), general weakness (Dourbalya), nervous debility, fatigue, and immune dysfunction[2]. External factors such as pollution, poor diet, smoking, alcohol consumption, stress, and chronic infections increase oxidative stress, making individuals more susceptible to inflammatory disorders, neurodegenerative diseases, cardiovascular conditions, and weakened immunity[3].

Conventional medicine relies on synthetic antioxidants such as vitamin C, vitamin E, and glutathione, but their long-term efficacy and safety remain questionable[4]. Some studies suggest that excessive use of synthetic antioxidants may lead to pro-oxidant effects, disrupting natural metabolic balance[5]. Ayurvedic medicine, on the other hand, offers a holistic approach by using natural herbs and minerals to neutralize free radicals, restore energy balance, and enhance immunity[6].

The Ayurvedic Perspective on Oxidative Stress and Vitality

Ayurveda classifies oxidative stress-related conditions under Vata-Pitta disorders, where excess heat (Pitta) and dryness (Vata) lead to cellular degeneration, fatigue, and tissue depletion[7]. According to Ayurvedic principles, antioxidant-rich formulations act as Rasayana (rejuvenative therapies) that promote longevity, tissue repair, and immune resilience[8]. Ayurvedic texts such as the Charaka Samhita and Sushruta Samhita describe the role of antioxidant herbs and minerals in reducing oxidative stress, improving digestion (Agni), and enhancing **Ojas (vitality and immunity)**[9].

One such Rasayana-based formulation is the Total Antioxidant Capsule, which contains a blend of powerful Ayurvedic herbs and minerals known for their anti-inflammatory, rejuvenative, and immune-enhancing properties. The key ingredients include Amalaki (Emblica officinalis), Guduchi (Tinospora cordifolia), Ashwagandha (Withania somnifera), Haridra (Curcuma longa), and Pippali (Piper longum), which have been scientifically validated for their antioxidant, anti-inflammatory, and immune-boosting effects[10].

Scientific Evidence Supporting Ayurvedic Antioxidants

Modern research has confirmed the efficacy of several Ayurvedic herbs in neutralizing free radicals, reducing inflammation, and preventing oxidative damage.

- Amalaki (Emblica officinalis) is a rich source of vitamin C, flavonoids, and polyphenols. Studies have shown that it enhances glutathione levels, reduces lipid peroxidation, and strengthens immune response[11].
- Guduchi (Tinospora cordifolia) acts as a powerful adaptogen and immunomodulator, promoting cellular repair, reducing oxidative stress, and improving energy metabolism[12].
- Ashwagandha (Withania somnifera) is known for its anti-stress and neuroprotective effects, helping to reduce

cortisol levels, improve mitochondrial function, and enhance cognitive performance[13].

- Haridra (Turmeric, Curcuma longa) contains curcumin, a potent anti-inflammatory and antioxidant compound that protects against neurodegeneration, liver toxicity, and metabolic dysfunction[14].
- Pippali (Piper longum) is used in Ayurveda for its bioenhancing effects, increasing the bioavailability of other antioxidants while reducing oxidative stress in the liver and blood vessels[15].

The Need for Clinical Validation of Total Antioxidant Capsule

Despite centuries of use, modern clinical validation is essential to scientifically establish the efficacy and safety of Ayurvedic antioxidant formulations. The present study, a Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial, was designed to evaluate the effectiveness of Total Antioxidant Capsule in reducing oxidative stress and improving overall vitality[16].

The trial recruited 20 patients suffering from oxidative stress-related conditions such as anemia, muscle fatigue, nervous debility, and weakened immunity. Participants were administered 1-2 capsules of Total Antioxidant Capsule twice daily with lukewarm water for 30 days. Clinical and laboratory assessments were conducted on Day 1 (Baseline) and Day 30 (End of Trial), monitoring key biomarkers such as antioxidant enzyme levels, inflammation markers, hemoglobin levels, and immune function[17].

As the global burden of oxidative stress-related diseases continues to rise, there is an urgent need for safe, natural, and effective antioxidant therapies. Total Antioxidant Capsule, formulated with clinically validated Ayurvedic herbs, provides a holistic solution for reducing oxidative damage, enhancing energy levels, and strengthening immunity. This clinical validation study aims to provide scientific evidence supporting the efficacy of Total Antioxidant Capsule, contributing to the integration of Ayurvedic medicine into modern preventive healthcare[18].

METHOD AND MATERIALS

Description of the population to be studied

The population of Salem city is more than 10,00,000, and the estimated prevalence rates of patients with “Rakthakshaya, Paanduroha (Anemia), Dhathukshaya (muscle wasting), Dourbalya (General weakness), Nervous debility, and fatigue”, who require enhancing their Immune function with herbal Anti inflammatory treatment, shall be more than 30 % in the area. To recruit the participants, we had advertised in the Social media (friend's groups, Local groups, Private Siddha/Ayurveda doctor groups, and on the Facebook pages ofSiddha/Ayurveda hospitals and creating awareness in public exhibitions.

Responsibility of potential risks and benefits, if any, to human subjects.

As per Siddha/Ayurveda textual references found in First schedule (section 3a) of Drugs and cosmetic act 1940, and scientific research studies done anywhere regarding the herbal ingredients found in the formula supplied by the manufacturing unit, an Undertaking has been obtained from the Manufacturer of the product that the Sample supplied for clinical trials contains only the herbal ingredients mentioned in the references found in first schedule Siddha/Ayurveda classical texts.

The Clinical research center has recruited the patients willing for the study after obtaining their written consent and provided the medicine in the prescribed dosage indicated in the package under the supervision of qualified Siddha/Ayurveda physician.

It has been clarified to the manufacturer that any Metals if included in the formula shouldconduct Toxicity studies and Pre-clinical animal studies before conducting clinical trials, and it was also clarified that the Manufacturer of the product is solely responsible for potential risk - if any, to human subjects undergoing this clinical study.

Quality control and quality assurance: The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The label should necessarily contain the word "For Clinical studies only".

Description of and justification for, the route of administration, dosage, dosage regimen, and treatment period

Route of Administration Dosage - Oral usage
Dosage - 1-2 capsules bds with 100 ml lukewarm water.
Dosage regimen - Morning and night, after food
Treatment period - 30 days

Trial study center: The centre of study is, Outpatient department. CRO - Ashram Siddha research institute, Swarnapuri, Salem city, Salem district.

IEC clearance: The prospective Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is duly approved by the INSTITUTIONAL ETHICAL COMMITTEE FOR CLINICAL RESEARCH OF THE CRO, Ashram Siddha Research Institute, constituted under Rule-7 and registered under Rule-8 of The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health and Family welfare, Govt. of India as per Ethical guidelines for Biomedical Research on Human subjects 2006 issued by AYUSH-ICMR guidelines. All patients were obtained with written informed consent.

Sample size and Period of study

Enrollment: 20 patients
Study Start Date: 29.11.2024
Study Completion Date: 31.12.2024

Screening of Patients for study: In the present study, patients suffering from symptoms like "Rakthakshaya, Paanduroha (Anemia), Dhathukshaya (muscle wasting), Dourbalya (General weakness), Nervous debility, and fatigue", who require enhancing their Immune function with herbal Anti inflammatory treatment, was taken for study. The Inclusion and exclusion were made by recording their past history and through clinical examination. After recruitment, all follow-up visits were performed at the same hospital by qualified Siddha/Ayurveda graduate investigators in keeping with the protocol.

Obtaining patient consent: Whenever a patient is included in the study a consent form in his mother tongue (enclosed) detailing the procedures with side effects if any, benefits from the treatment, was explained and details of the follow up visit was also explained. The procedure for referral clause, withdrawal, and adverse effects was explained thoroughly.

Criteria for Inclusion: Patients above 20 years and below 60 years, suffering from clinical symptoms like "Rakthakshaya, Paanduroha (Anemia), Dhathukshaya (muscle wasting),

Dourbalya (General weakness), Nervous debility, and fatigue", was taken for study.

Criteria for Exclusion:

Participants will be excluded if they are above 65 years, experiencing or have a history of the following: Osteo arthritis, history of drug/alcohol abuse, night/shift-work employment, Diabetic complications, Psoriatic arthritis and any endocrine disorders.

Criteria for withdrawal:

During the course of the trial, if any serious conditions develop (or) the symptoms aggravate which requires urgent treatment, such subjects may be withdrawn from the trial.

Outcome Measure

Routine Examination and assessment as per Indian Medicine Physiology

The complete History and physical examination of the patients along with Envagaithaervu, tridoshanaadi, saptha dhatu thaervu etc. were recorded in a case sheet on first day. The second Clinical assessment was done on 30th day of treatment.

Blood test:

Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators.

Interventions: The patients were provided with Proprietary Ayurvedic Medicine — TOTAL ANTIOXIDANTCAPSULE, and advised to take 1-2 capsules, Morning and evening.

As Lifestyle management with diet and exercise can improve the condition and patient self- management life style changes were advised.

Success indicators:

Reduction of minimum 10 percent in symptoms at baseline and at the completion of treatment in the words of the patient, and measured as per the physician's conscience, can be taken as Success indicator.

Laboratory Investigations and discussion:

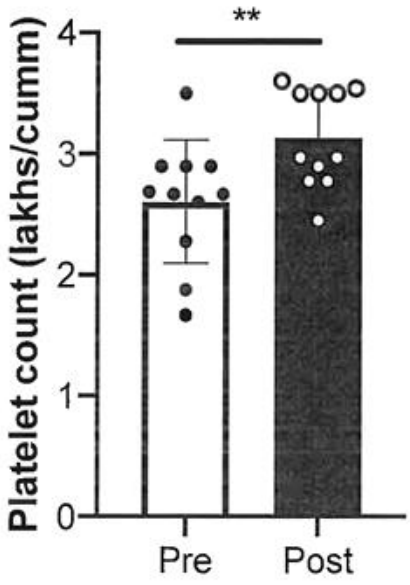
Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein.

Samples were analyzed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators.

SPECIMEN	TEST NAME	METHOD	VALUE	UNITS	REF.RANGE
HAEMATOLOGY					
Blood	Hemoglobin	Sysmex XS 8ooi	..	g/dl	13.0-17.0
Blood	RBC count	Sysmex XS 8ooi	..	mil/cu.P	4.5-6.5
Blood	Haematocrit (PCV)	Sysmex XS 8ooi	..	%	40-54
Blood	MCV	Sysmex XS 8ooi	..	fl	75-95
Blood	MCH	Sysmex XS 8ooi	..	picogram	27-32
Blood	MCHC	Sysmex XS 8ooi	..	g/dl	32-36
Blood	Red cell width	Sysmex XS 8ooi	..	%	11-16
Blood	Platelet counts	Sysmex XS 8ooi	..	lakhs/cumm	1.5-4.0
Blood	Total WBC count	Sysmex XS 8ooi	..	cells/cumm	4000-11000
Blood	Differential count (DC)	VESMATIC ESAY			
	Neutrophils		..	%	40-80
	Lymphocytes		..	%	20-40
	Eosinophils		..	%	01-06
	ESR		..	mm/hr	0-10
CLINICAL PATHOLOGY URINE COMPLETE					
Urine	Protein	Combur UX strip (ROCHE)		..	
Urine	Ketone			..	
Urine	Pus cells			..	/Hpf
Urine	Epithelial cells			..	/Hpf

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



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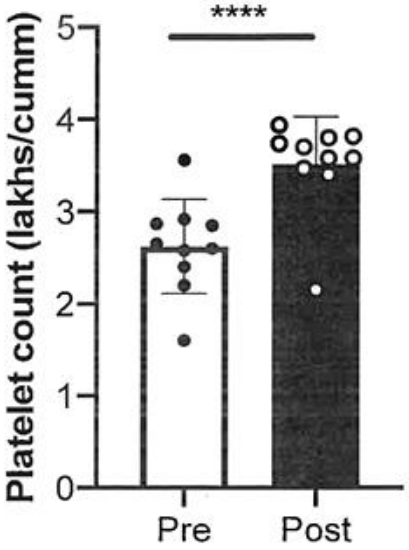

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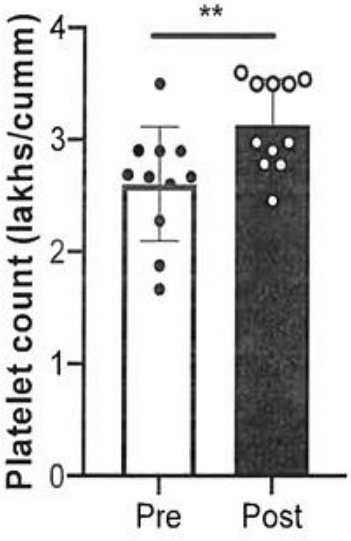

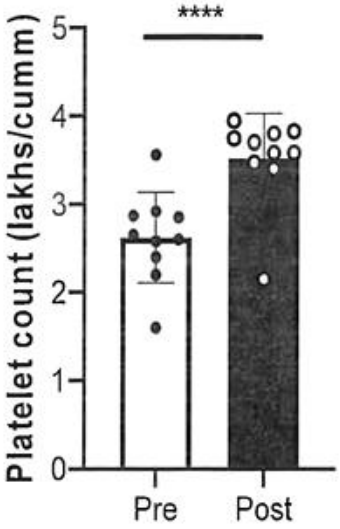

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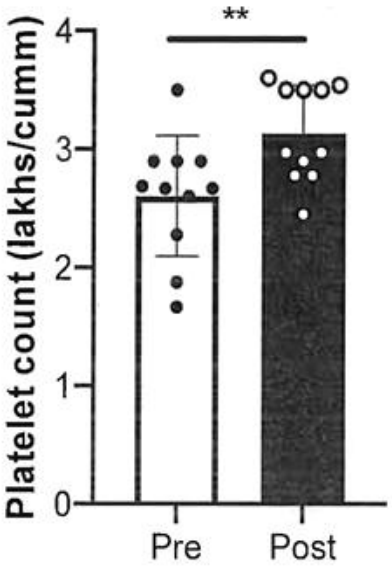

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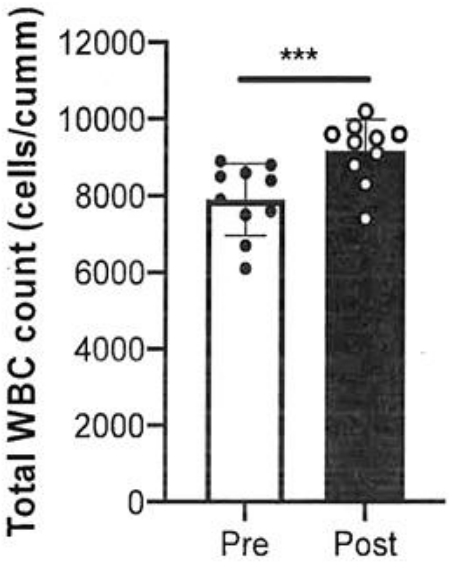

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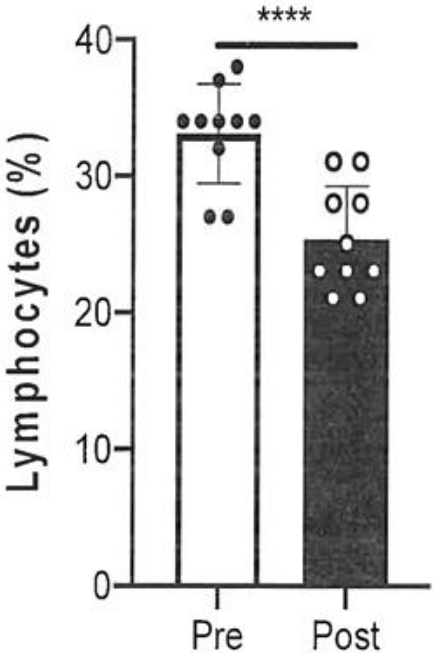

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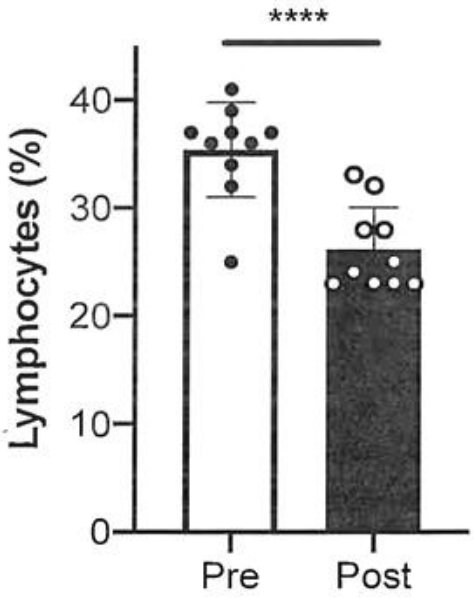

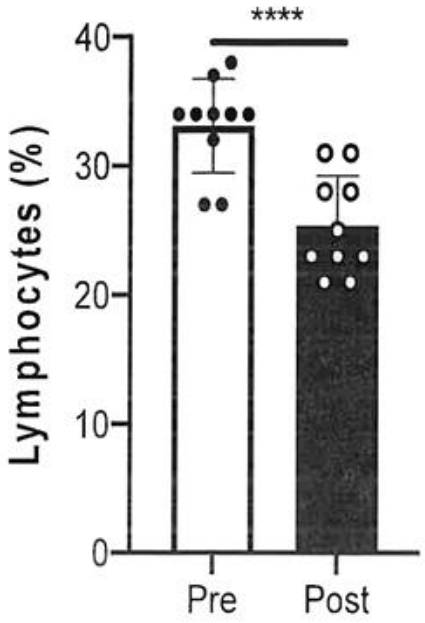

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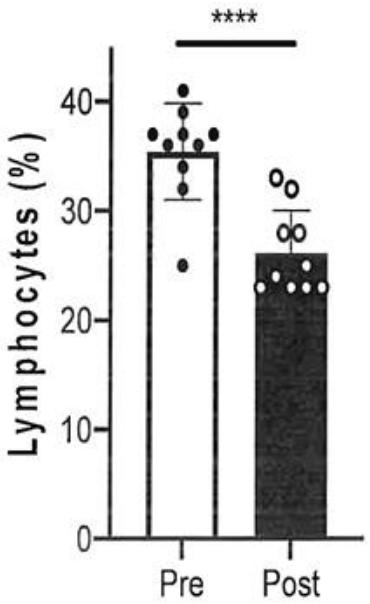

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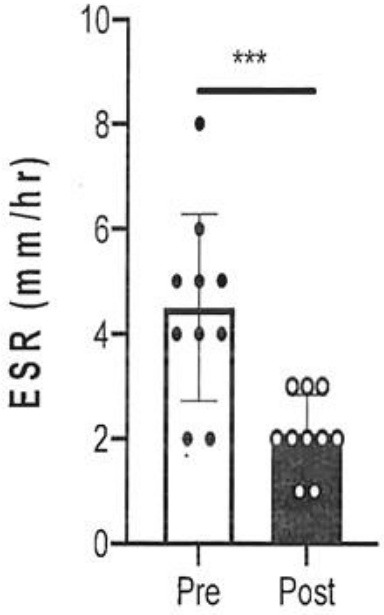

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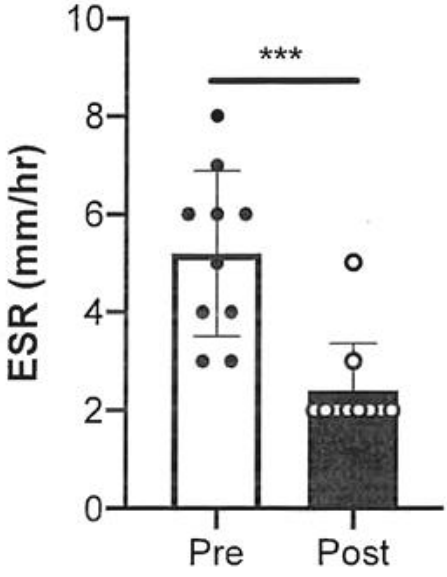

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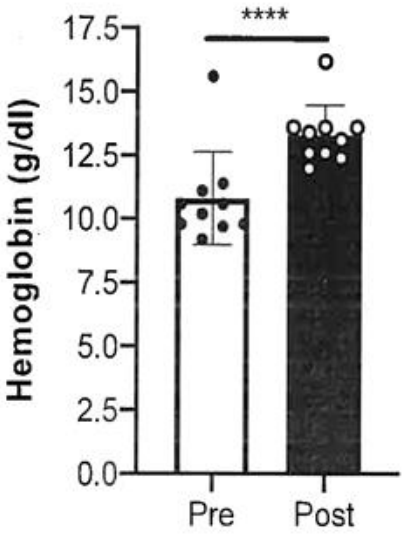

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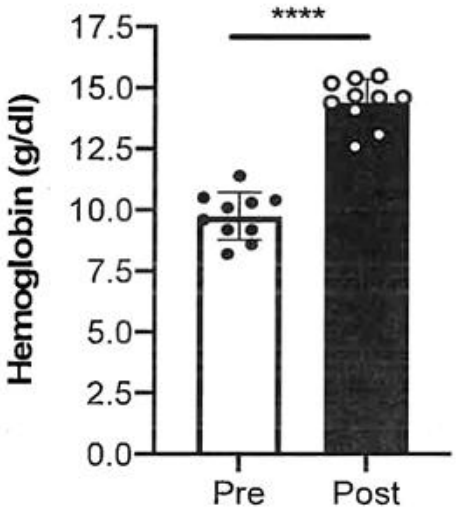

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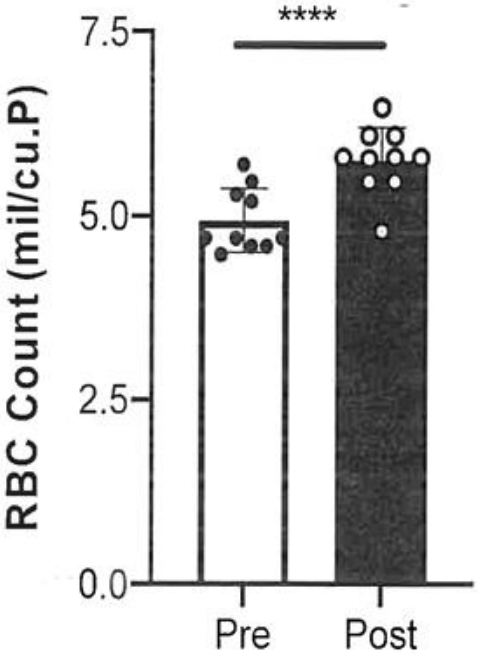

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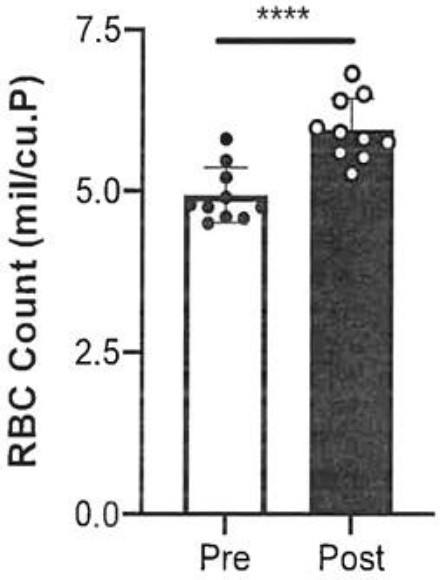

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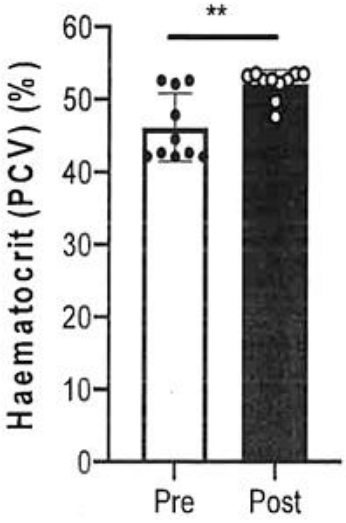

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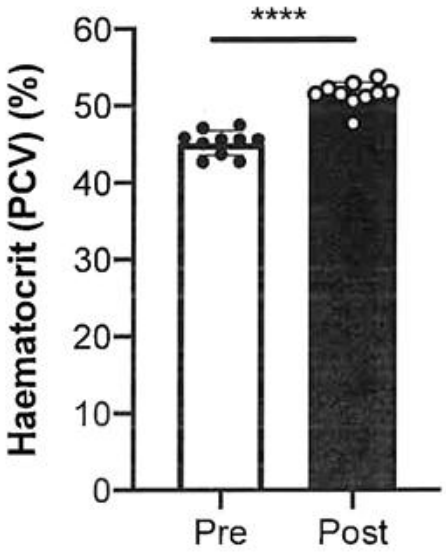

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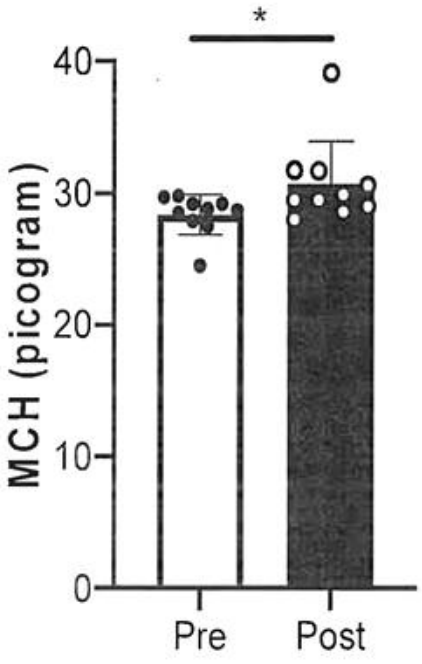

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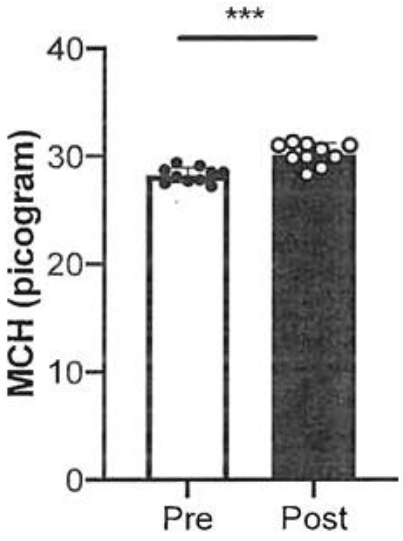
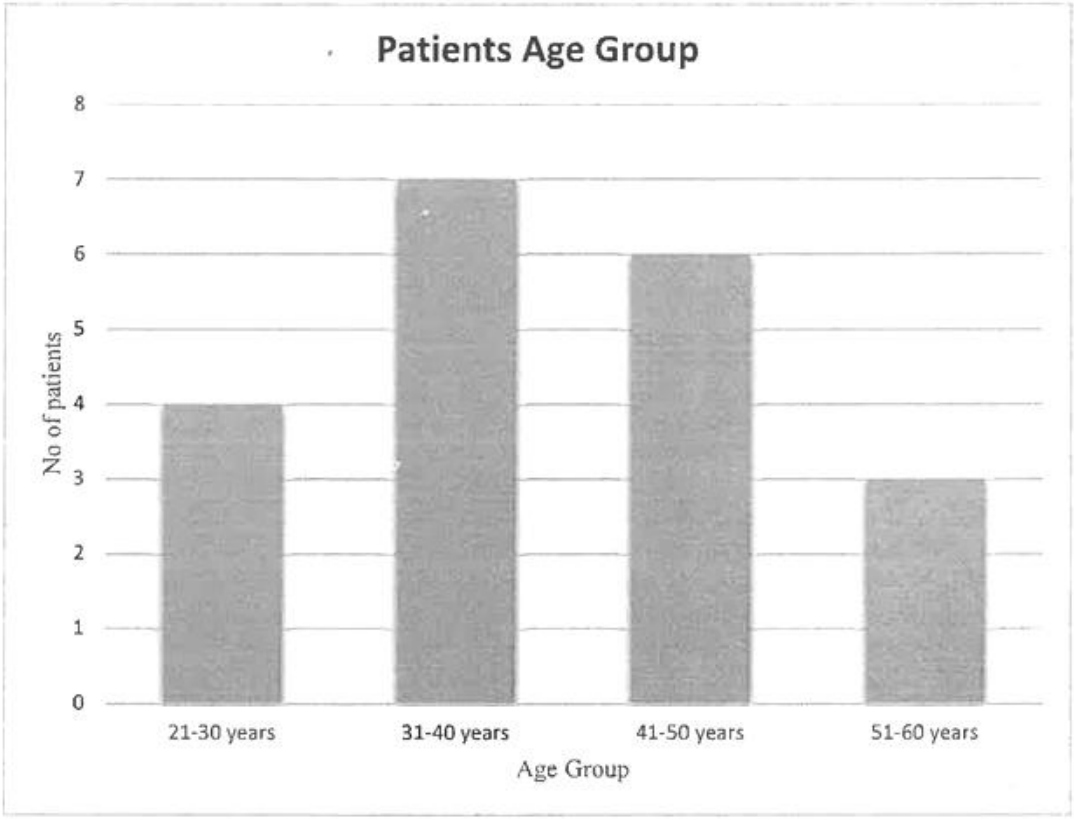


Cohort B

Discussion, Statistical Analysis & Interpretation of the Results Obtained

TABLE -A ; Age group of Patients (20)

Age group	Total	%
25 – 40	06	30%
41 – 60	14	70%

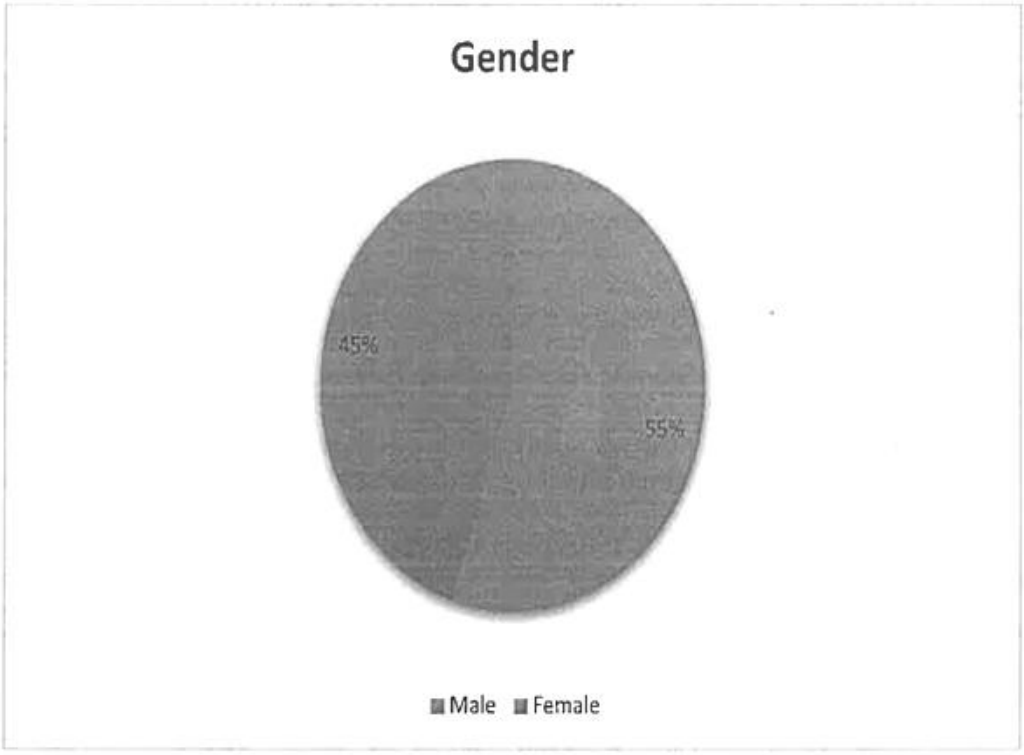


Interpretation

From the above chart, the sample size of the study is 20, out of which 06 patients belong to age group 25-40 years, and 14 patients belong to age group 41-60 years .

TABLE – B ; Gender of the Patients (20)

Sex	Total	%
Male	11	55%
Female	9	45%

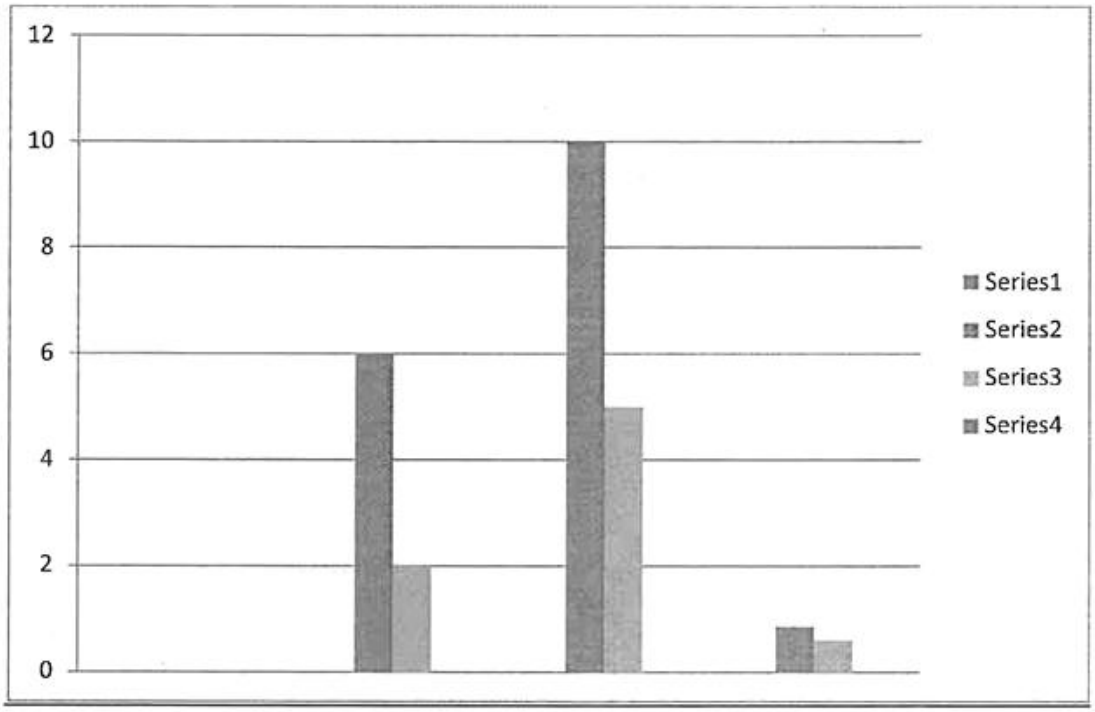


Interpretation

From the above chart, the sample size of the study is 20, out of which there are about 55% male and 45% female

Table-C, Improvement from "Rakthakshaya, - in One month (20)

Onset	Age group	Total
Acute onset (within 1 week)	21-30 years	5
	31-40 years	12
Chronic onset (more than 1 week)	21-30 years	1
	31-40 years	2

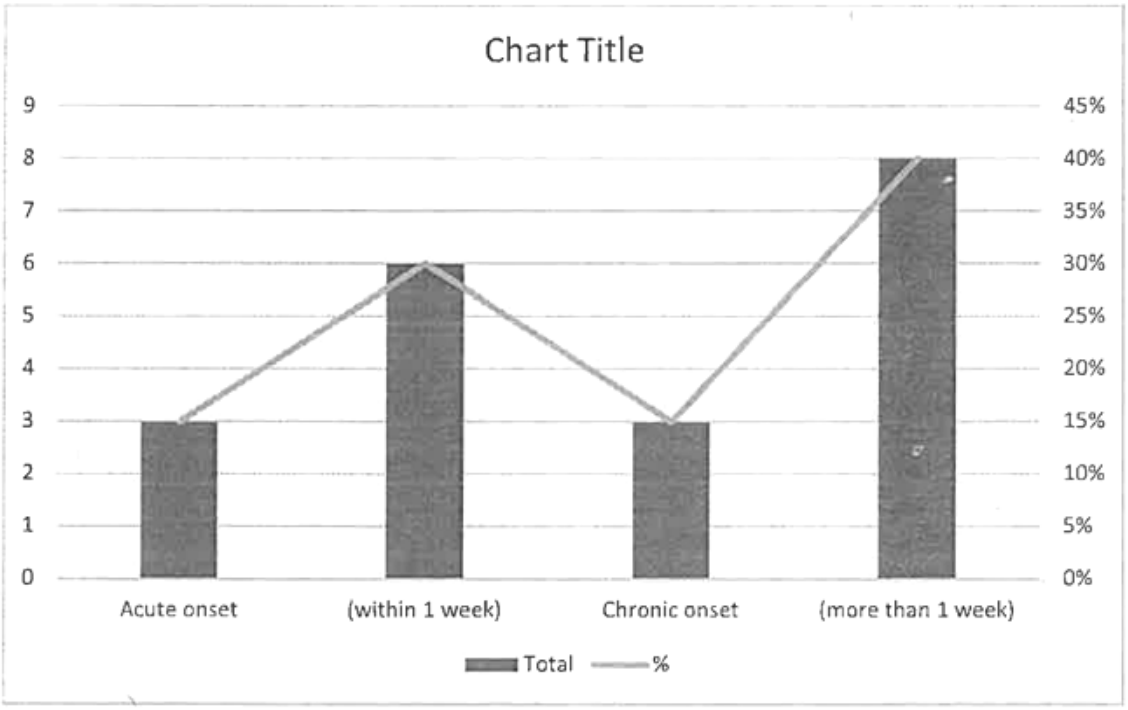


Interpretation

From the above chart, the sample size of the study is 20, out of which 17 patients and 3 patients respectively who had been taken for study had improvement in the symptoms within one week and more than one week.

TABLE – D; Improvement from Paanduroha (Anemia), in One month (20)

Onset	Age group	Total
Acute onset (within 1 week)	21-30 years	4
	31-40 years	8
Chronic onset (more than 1 week)	21-30 years	2
	31-40 years	2

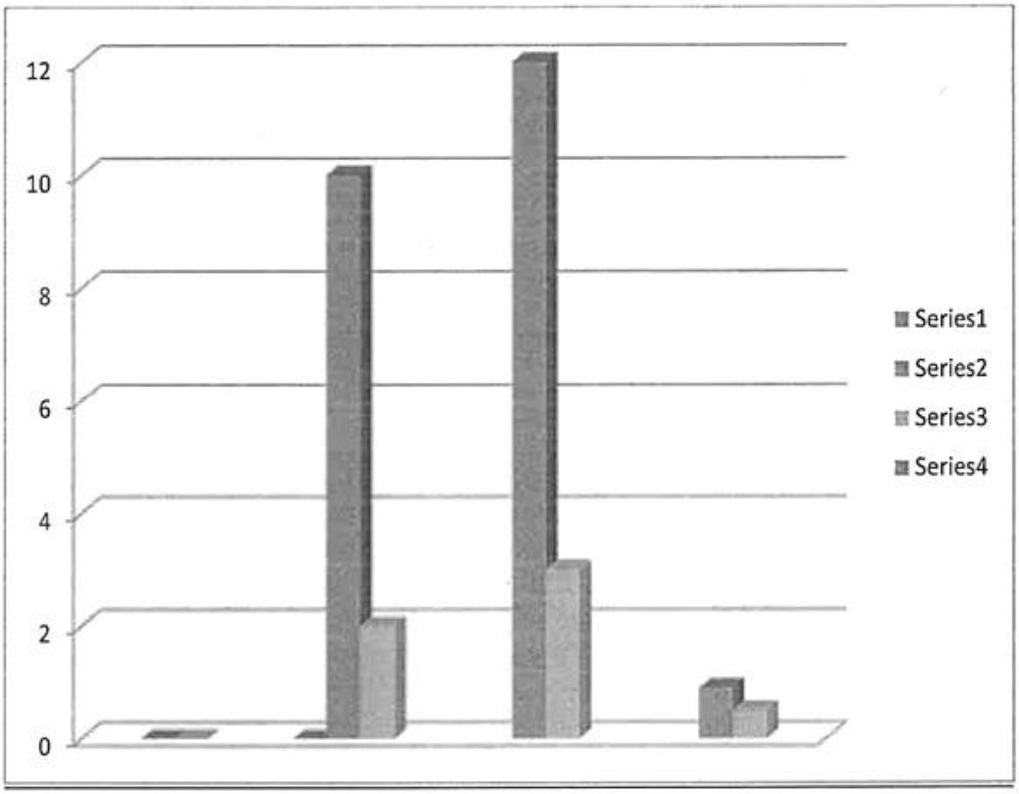


Interpretation

From the above chart, the sample size of the study is 20, out of which 12 patients belonging to age group 25-40 years and 4 patients belonging to age group 41-60 years respectively who had been taken for study had improvement in the symptoms within one week and more than one week.

TABLE – E ; Improvement of *Dhathukshaya (muscle wasting), Dourbalya (General weakness), Nervous debility, and fatigue"*,in One month (20)

Age group	Improvement in symptoms 2 weeks , 4 weeks.		% of Improvement
21-45	10	12	90 %
45-60	2	3	50 %

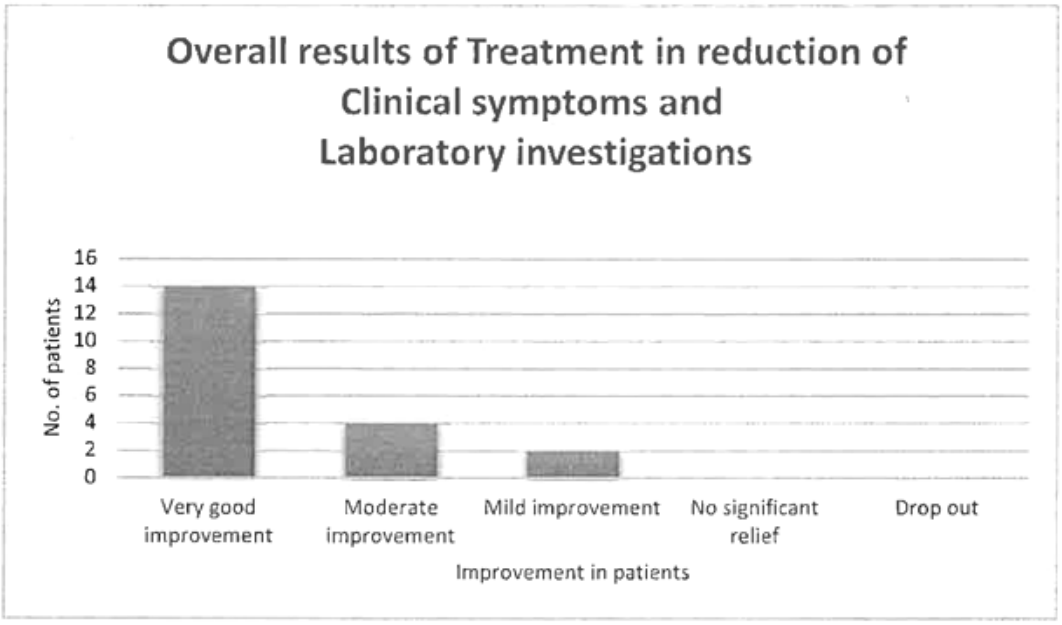


Interpretation

After the treatment of 30 days, 90% belonging to age group 25-40 years and 50% belonging to age group 41-60 years respectively had significant improvement of clinical symptoms.

Table – 7: Overall results of Treatment in reduction of Clinical symptoms and Laboratory investigations in patients treated (Total 20 patients)

Results	No. of patients	Percentage
Very good improvement	16	80 %
Moderate improvement	03	15 %
Mild improvement	01	5 %
No significant relief	0	0 %
Drop out	0	0 %



Interpretation

From the above chart, the sample size of the study is 20, out of which after the treatment of 30 days, 16 patients (80%) had very good improvement of symptoms and 3 patients (15%) had moderate improvement and 1 patient had mild improvement during the study.

Direct access to source data/documents: We hereby agree that the investigator(s)/ institution will permit trial-related monitoring, audits, institutional review board/independent ethics committee review, and regulatory inspection(s), by the Research Council/Department of AYUSH providing direct access to source data/documents.

Quality control and quality assurance: The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The label should necessarily contain the word "For Clinical studies only".

Compensation to the Participant: As per GCP guidelines the subjects were compensated for the inconvenience and time present in connection with their participation in this clinical trial by signing a Voucher after payment of compensation.

Participant protections and ethics: To protect human participants, the protocol was written according to general ethical guidelines, such as the Declaration of Helsinki and Good Clinical Practice and" was approved by the institutional ethical committee of the organization. The study participant consent process includes information about potential risks, benefits, alternatives, and responsibilities during the trial.

Before participants agree to participate in this trial, researchers will explain this information in detail in person.

Data and safety monitoring: Regular monitoring that will be clarified in a standard operating procedure will be conducted to ensure good data quality. Monitors from IEC will evaluate whether the case report forms areproperly written and whether the recruiting and treatment procedures are adequatelyperformed according to the protocol. Investigators will be contacted to discuss whether it is necessary to revise the study protocol or inclusion criteria and other important issues. The investigators andindependent researchers will assess the progress of the clinical trial and severeadverse events and determine whether they are acceptable and whether it will be necessary for the trial to be modified or stopped.

Case Sheets prepared for each patient and all the records and vouchers will be retained with the treatment centre for Three years.

CONCLUSION

Results of the Phase-II A, Single center, Open label, Therapemleexplorato cllmeattrials.The current Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trialsis designed to evaluate the efficacy of Proprietary Ayurvedic Medicine- TOTAL ANTIOXIDANT CAPSULE, Manufactured by VIJAYANI NUTRACEUTICALS PW LTD, No.2B/1,2B/2, 6th street, 3rd Main road, Ambattur Industrial estate South, Ambattur, Chennai-600058. Tamilnadu on patients suffering from clinical symptoms of "Rakthakshaya, Paanduroha (Anemia), Dhathukshaya (muscle wasting), Dourbalya (General weakness), Nervous debility, and fatigue".

By consolidating the results obtained in the clinical investigations and laboratory investigations, it is hereby concluded that the Proprietary Ayurvedic Medicine- TOTAL ANTIOXIDANT CAPSULE, is highly effective in controlling Clinical symptoms of "Rakthakshaya, Paanduroha (Anemia), Dhathukshaya (muscle wasting), Dourbalya (General weakness), Nervous debility, and fatigue". It was clinically found to provide Anti inflammatory action and helps to enhance the patient's Immune function, in the recruited patients.

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