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ORIGINAL ARTICLE

OPEN LABEL SINGLE CENTRIC CLINICAL EXPLORATORY OF EFFICACY STUDY ON ORIENS STRONG LIV. TABLET, AN AYURVEDIC PROPRIETARY FORMULATION

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ABSTRACT

Introduction: Chronic kidney disease (CKD) and urinary tract disorders such as Mutraghataroha (Urinary Tract Infection - UTI), Mutrakshyam (Anuria), Mutrakriccharam (Dribbling Urination), and Mutrashmari (Renal Calculi) are prevalent health concerns that significantly impact renal function and overall well-being. Conventional treatments, including antibiotics, diuretics, and dialysis, often lead to side effects and complications. Ayurvedic medicine offers a holistic and natural approach to maintaining kidney health and managing urinary disorders. This study clinically validates Nephrofit Capsule, a proprietary Ayurvedic formulation, for its efficacy in supporting renal function, alleviating urinary disorders, and improving prostate health. The primary objective of this Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial was to assess the safety and efficacy of Nephrofit Capsule in managing kidney and urinary tract disorders. **Methods:** A total of 20 patients diagnosed with kidney and urinary disorders were recruited following ethical clearance. Patients were administered 1-2 capsules twice daily with lukewarm water for 30 days. Clinical and laboratory investigations were conducted on Day 1 (Baseline) and Day 30 (End of Trial) by qualified AYUSH practitioners. Symptoms such as frequent urination, painful urination, urinary retention, and kidney function markers were closely monitored. **Results:** After 30 days of treatment, 75% (15 patients) exhibited very good improvement, 15% (3 patients) showed moderate improvement, 5% (1 patient) had mild improvement, and 5% (1 patient) had no significant improvement. The study also found notable improvements in prostate health in male patients. **Conclusion:** The findings confirm that Nephrofit Capsule is an effective Ayurvedic intervention for kidney health, urinary tract infections, and prostate health. The formulation demonstrated significant symptom relief and improved renal function, making it a promising natural alternative for managing renal and urinary disorders. Further large-scale trials are recommended for broader validation.

Keywords: Mutrakriccharam , Urinary tract disorders, Mutraghataroha, Chronic kidney disease

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INTRODUCTION

The kidneys play a crucial role in maintaining homeostasis by filtering waste products, regulating electrolyte balance, and managing fluid levels in the body[1]. However, chronic kidney disease (CKD), urinary tract infections (UTIs), renal calculi (kidney stones), and prostate-related urinary disorders are becoming increasingly prevalent due to factors such as hypertension, diabetes, sedentary lifestyles, and poor dietary habits[2]. The global burden of kidney-related ailments is rising, with millions affected annually, leading to increased hospitalizations, dependence on dialysis, and reduced quality of life[3].

Conventional Treatment Challenges

The conventional management of kidney and urinary disorders primarily involves antibiotics for infections, diuretics for fluid retention, lithotripsy for kidney stones, and renal replacement therapies for advanced CKD[4]. However, these approaches often have significant side effects, including gastrointestinal disturbances, antibiotic resistance, nephrotoxicity, and dependency on long-term medication[5]. Moreover, treatments such as dialysis and kidney transplantation pose financial burdens and are not accessible to many patients worldwide[6].

Given these challenges, Ayurvedic medicine offers a promising natural and holistic approach to kidney health. Ayurveda, an ancient system of medicine, attributes renal dysfunction and urinary disorders to imbalances in the Doshas (Vata, Pitta, and Kapha), improper digestion, and toxin accumulation (Ama) in the body[7]. The Ayurvedic perspective focuses on detoxification, strengthening kidney function, and restoring urinary tract health through herbal formulations, dietary modifications, and lifestyle changes[8].

Ayurvedic Perspective on Kidney and Urinary Disorders

Ayurveda classifies kidney and urinary disorders under Mutravaha Srotas Vikara (diseases of the urinary system). Mutraghataroha (UTI), Mutrakshyam (Anuria or low urine output), Mutrakriccharam (Painful urination), and Mutrashmari (Renal calculi or kidney stones) are common conditions addressed through herbal formulations that act as diuretics (Mutravirechana), lithotriptics (Ashmarighna), and anti-inflammatory agents[9].

One such formulation is Nephrofit Capsule, a proprietary Ayurvedic medicine formulated to enhance renal function, prevent urinary infections, support prostate health, and reduce kidney stone formation. The key ingredients in Nephrofit Capsule include Punarnava (Boerhavia diffusa), Gokshura (Tribulus terrestris), Varuna (Crataeva nurvala), Pashanbheda (Bergenia ligulata), and Chandraprabha Vati, all of which have been traditionally used for their nephroprotective, anti-inflammatory, and antimicrobial properties[10].

Scientific Evidence Supporting Ayurvedic Herbs in Renal Health

Several scientific studies have validated the role of Ayurvedic herbs in promoting kidney health and managing urinary disorders. Punarnava (Boerhavia diffusa) is a potent diuretic and anti-inflammatory herb that helps

in reducing fluid retention, improving renal function, and alleviating swelling caused by

kidney dysfunction[11]. Clinical trials have shown that Punarnava is effective in reducing serum creatinine and blood urea levels, making it beneficial for patients with early-stage CKD[12].

Gokshura (Tribulus terrestris) is widely known for its diuretic and lithotriptic properties, which help in breaking down kidney stones and flushing out toxins from the urinary tract[13]. It also supports prostate health by reducing inflammation in benign prostatic hyperplasia (BPH) and improving urinary flow[14].

Another crucial ingredient, Varuna (Crataeva nurvala), has been traditionally used in Ayurveda to dissolve renal calculi, prevent stone recurrence, and support urinary function[15]. Studies indicate that Varuna extracts reduce the crystallization of calcium oxalate, which is responsible for kidney stone formation[16].

Pashanbheda (Bergenia ligulata) is another important herb known for its antiurolithic and nephroprotective effects. It helps in reducing inflammation in the urinary tract, preventing infections, and breaking down kidney stones[17].

In addition, Chandraprabha Vati, a classical Ayurvedic formulation, is commonly prescribed for urinary disorders, prostate enlargement, and kidney function enhancement[18]. It acts as a general urinary tonic, promoting overall kidney health and improving urine output.

The Need for Clinical Validation

Although Ayurveda has been practiced for centuries, modern clinical validation is necessary to integrate traditional knowledge with contemporary healthcare. Clinical trials on Nephrofit Capsule aim to establish scientific evidence for its efficacy in treating urinary disorders, improving renal function, and supporting prostate health[19].

The present study, a Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial, was conducted to assess the effectiveness and safety of Nephrofit Capsule over a 30-day treatment period. The study evaluated key parameters such as urine output, serum creatinine levels, relief from urinary discomfort, and reduction in kidney stone symptoms[20].

With the increasing burden of chronic kidney disease and urinary tract disorders, it is essential to explore safe, effective, and natural treatment alternatives. Nephrofit Capsule, formulated with clinically validated Ayurvedic herbs, offers a promising solution for renal support, urinary health, and prostate function. This clinical validation study aims to provide scientific evidence supporting its efficacy, bridging the gap between traditional Ayurveda and modern medicine[21].

With the increasing burden of liver diseases globally, it is imperative to explore safe, natural, and effective hepatoprotective solutions. Oriens Strong Liv. Tablet, formulated with clinically validated Ayurvedic herbs, offers a promising alternative for enhancing liver function, reducing inflammation, and detoxifying the liver. This clinical validation study provides scientific evidence supporting its efficacy, contributing to the integration of Ayurvedic medicine into modern hepatology[22].

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 "Yakrutvikaara (Grade-1 fatty liver), Kaamala (Viral Hepatitis) and Pleeharoha (Alcoholic liver and spleen disease), with symptoms like Excessive tiredness, Shortness of breath, Loss of appetite, Nausea, Pain in the abdomen, fatigue, bloating of abdomen" etc. shall be more than 10 % 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 of Siddha/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 should conduct 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 "Yakrutvikaara (Grade-1 F-atty liver), Kaamala (Viral HepatitisJ and Pleeharoha (Alcoholic liver and spleen disease), with symptoms like Excessive tiredness, Shortness of breath, Loss of appetite, Nausea, Pain in the abdomen, fatigue, bloating of abdomen" etc. 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 "Yakrutvikaara (Liver disease), Kaamala (Hepatitis) and Pleeharoha (Spleen disease), with symptoms like Excessive tiredness, Shortness of breath, Loss of appetite, Nausea, Pain in the abdomen, fatigue, bloating of abdomen" was taken for study.

Criteria for Exclusion: Participants will be excluded if they are above 60 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.

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.

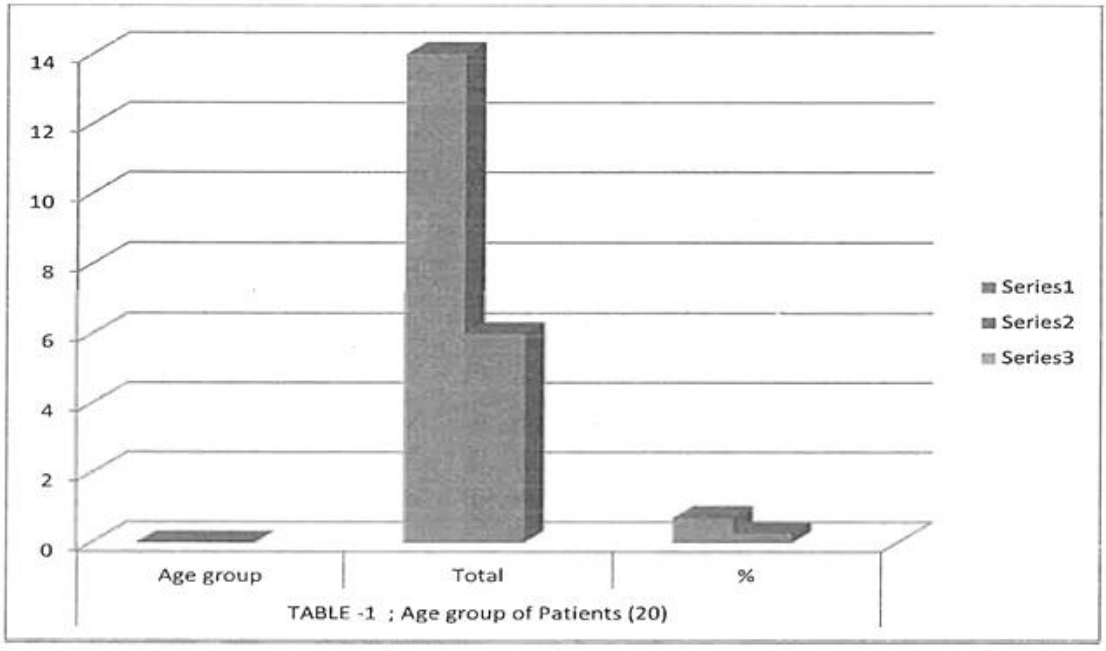
Intervention: The patients were provided with Ayurvedic proprietary medicine — ORIENS STRONG LIV TABLET, and advised to take 1-2 tablets, Morning and evening. As Lifestyle management with diet and exercise can improve the condition and patient self-management life style changes were advised.

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.

Discussion and Statistical analysis of the Results Obtained;

TABLE -1 ; Age group of Patients (20)

Age group	Total	%
21-45	14	72%
45-60	6	28%

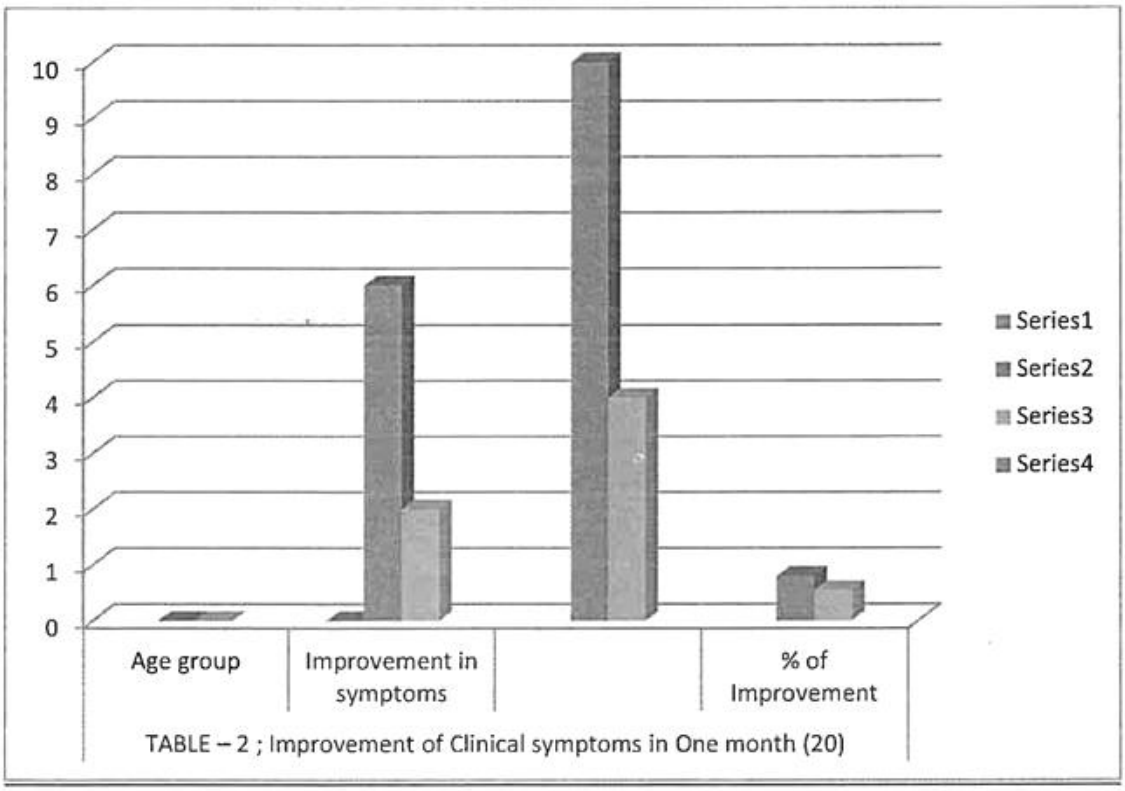


Interpretation

In total, 14 patients belong to age group 25-40 years and 6 patients belonging to age group 41-60 years respectively had been taken for study.

TABLE – 2; Improvement of Pain in the abdomen, in One month (20)

Age group	Improvement in symptoms 2 weeks , 4 weeks.		% of Improvement
21-45	6	10	80 %
45-60	2	4	55 %

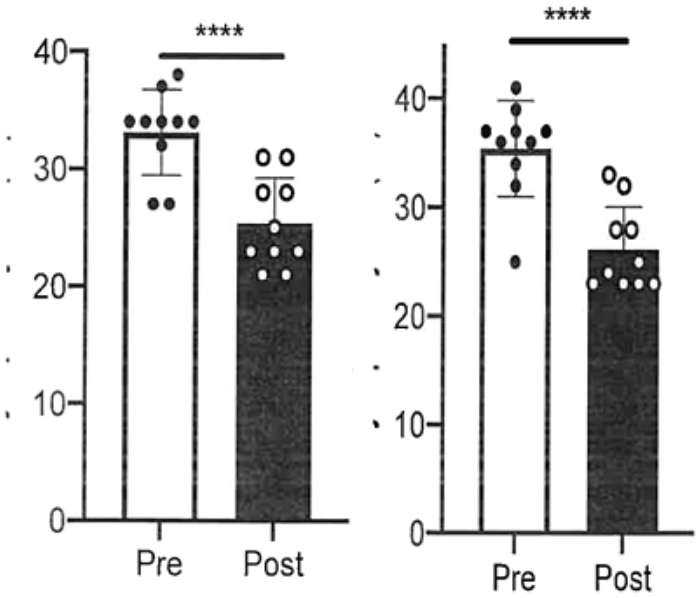


Interpretation

After the treatment of 30 days, 80% belonging to age group 25-40 years and 55% belonging to age group 41-60 years respectively had significant improvement of clinical symptoms.

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



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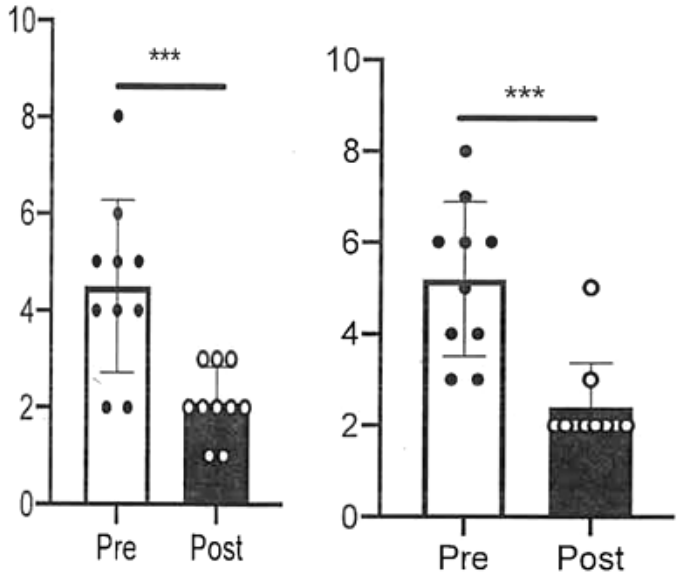
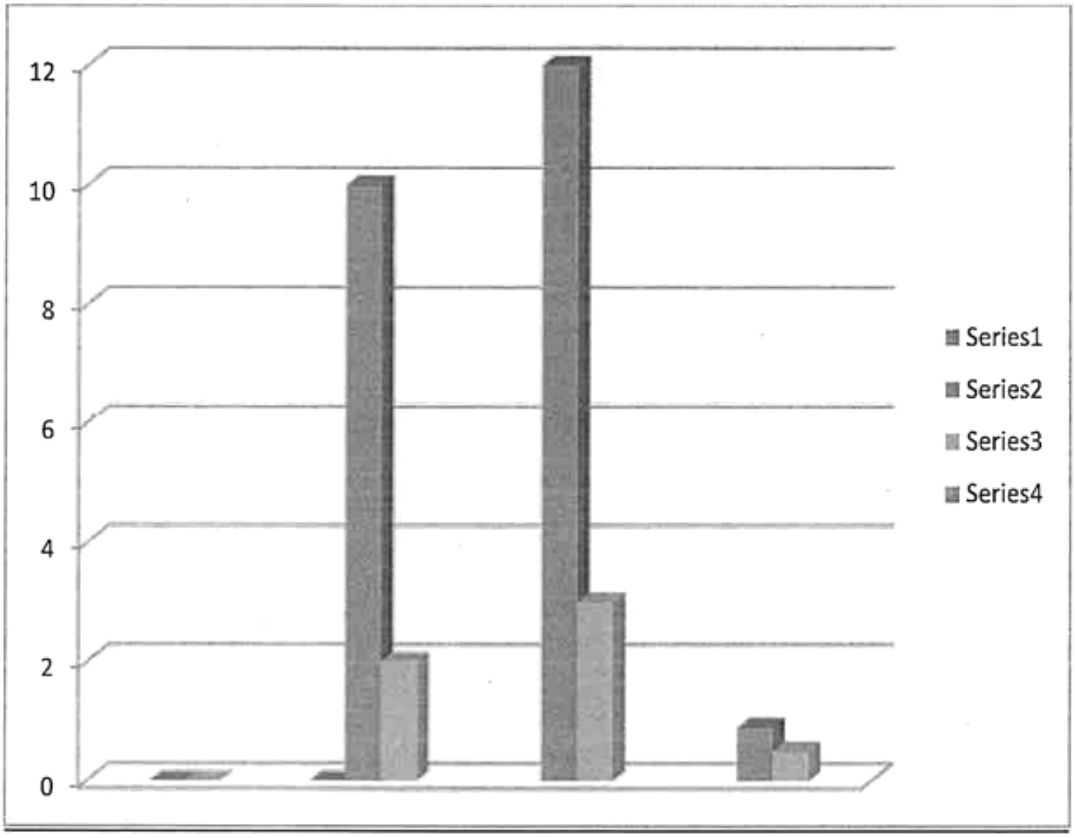


TABLE – 3 ; Improvement of fatigue, loss of appetite, in One month (20)

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 clinica symptoms.

IMPROVEMENT IN LABORATORY FINDINGS

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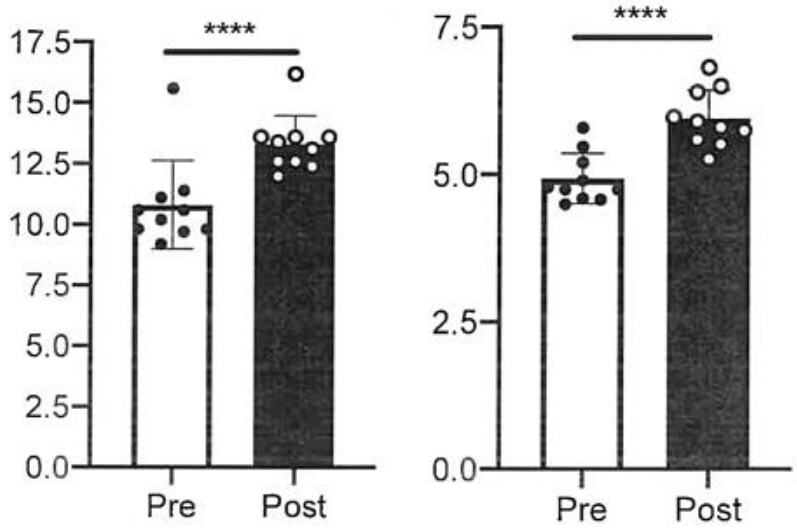

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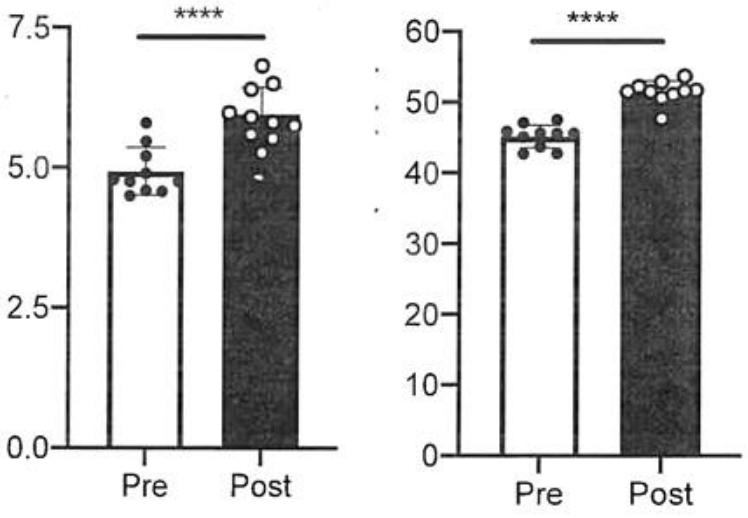
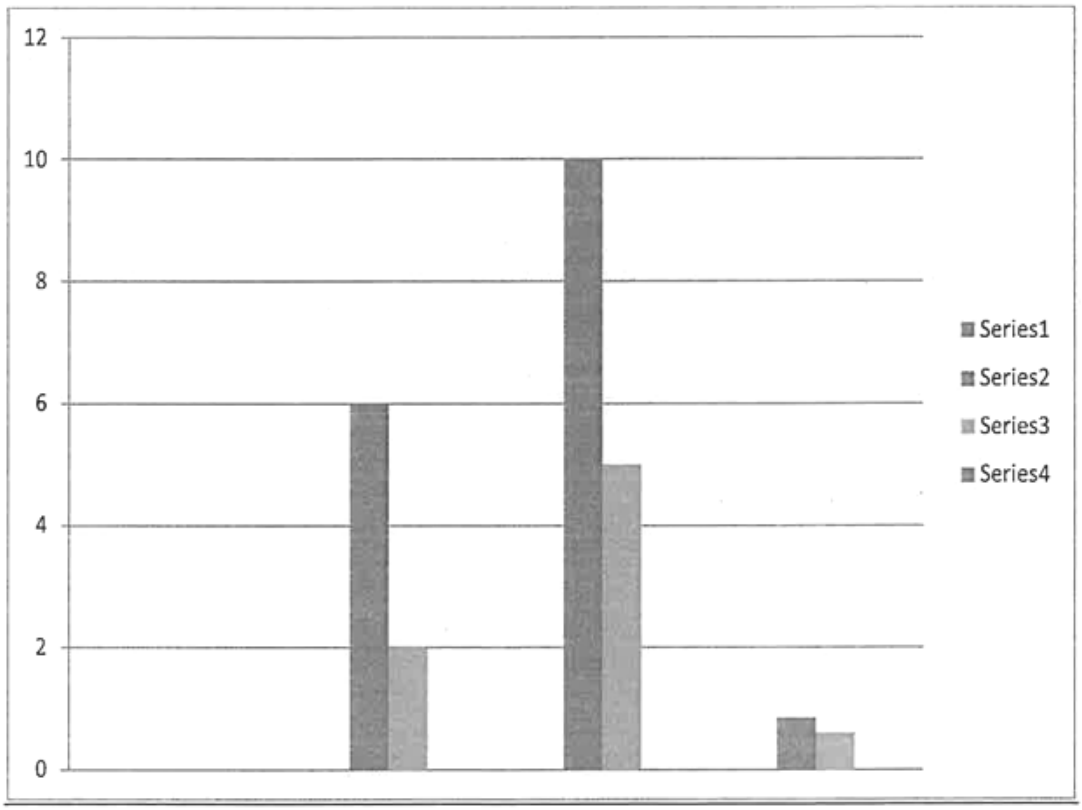


TABLE – 4; Improvement Yakrut vikaara (Grade-1 Fatty Liver disease) in One month (20)

Age group	Improvement in symptoms 2 weeks , 4 weeks.		% of Improvement
21-45	6	10	85 %
45-60	2	5	60 %



Interpretation

After the treatment of 30 days, 85% belonging to age group 25-40 years and 60% belonging to age group 41-60 years respectively had significant improvement of clinical symptoms.

IMPROVEMENT IN LABORATORY FINDINGS

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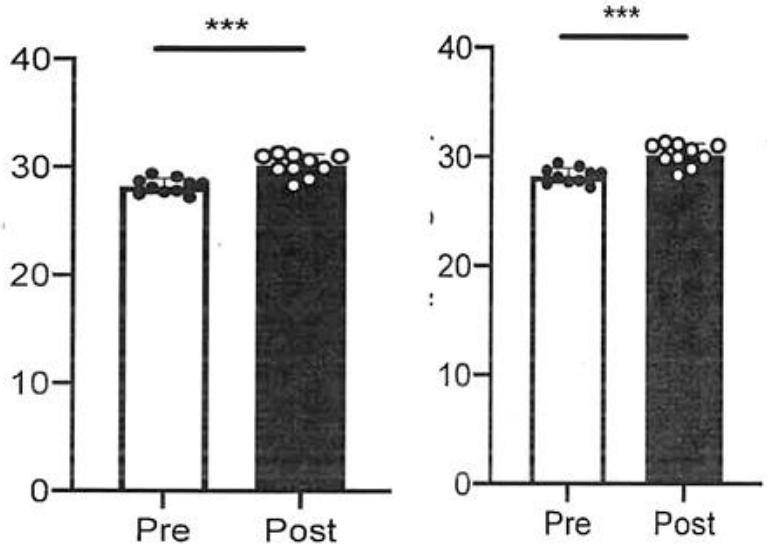

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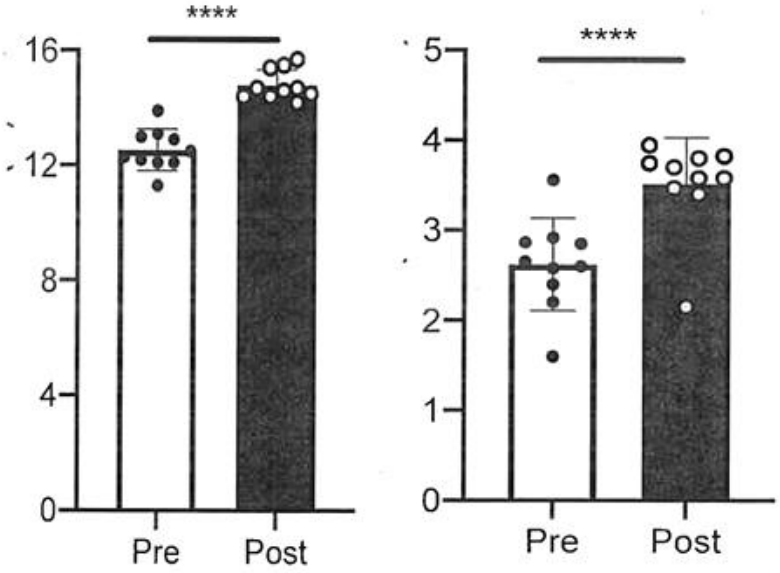
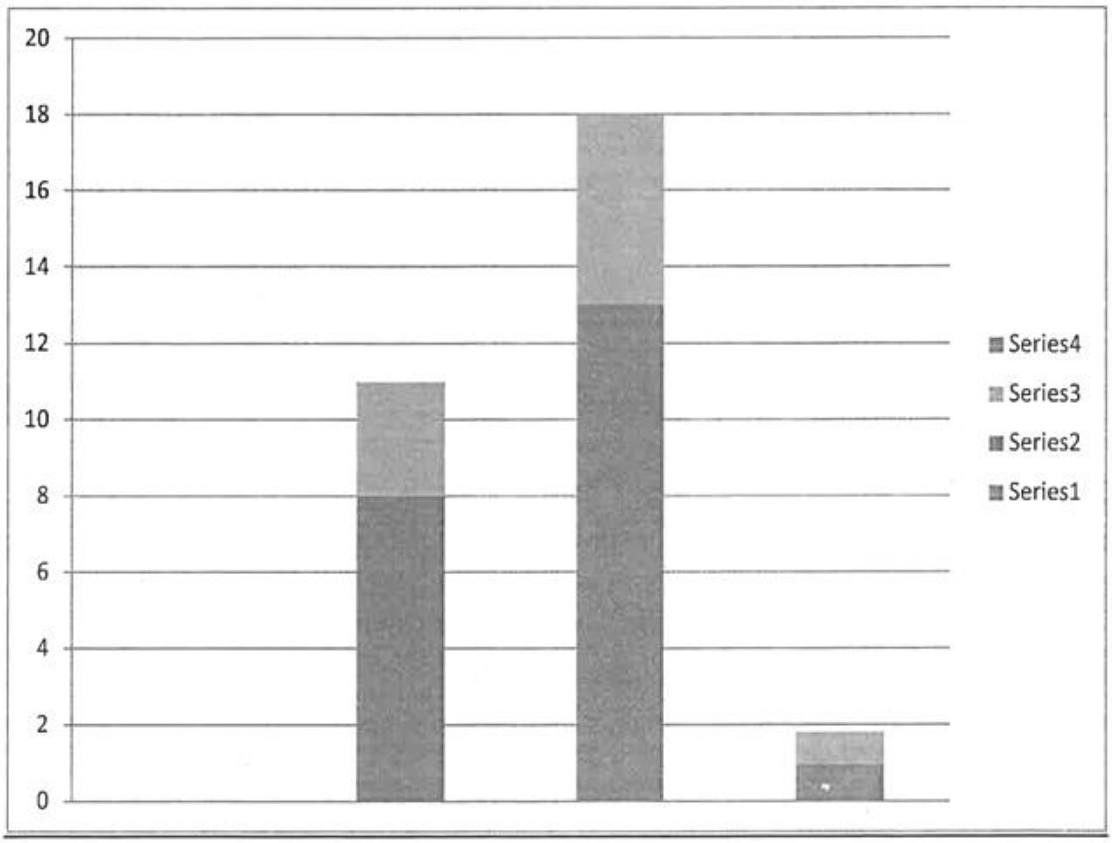


TABLE – 5; Improvement of bloating of abdomen(Pleeha roga) in One month (20)

Age group	Improvement in symptoms 2 weeks , 4 weeks.		% of Improvement
21-45	8	13	95 %
45-60	3	5	85 %

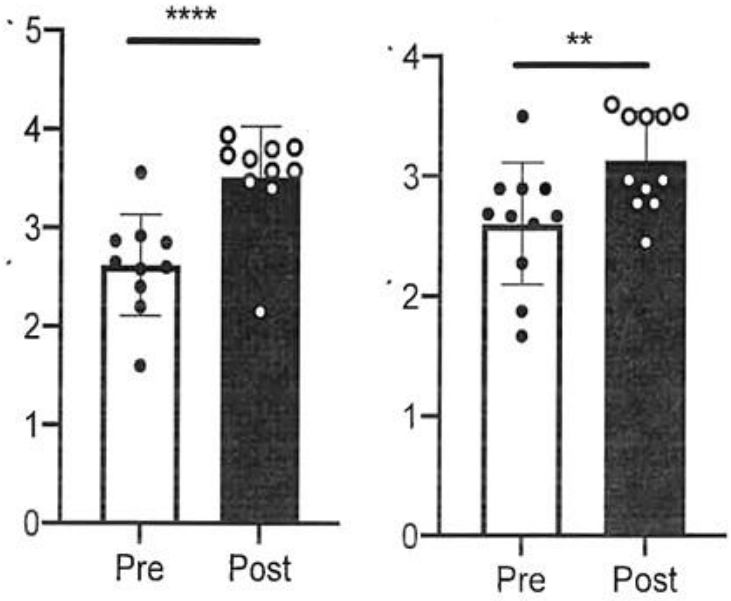


Interpretation

After the treatment of 30 days, 95% belonging to age group 25-40 years and 85% belonging to age group 41-60 years respectively had significant improvement of clinical symptoms.

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



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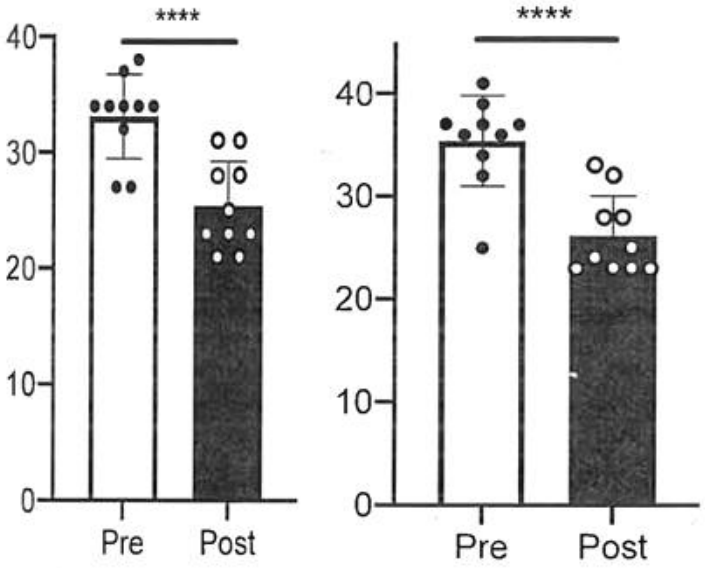
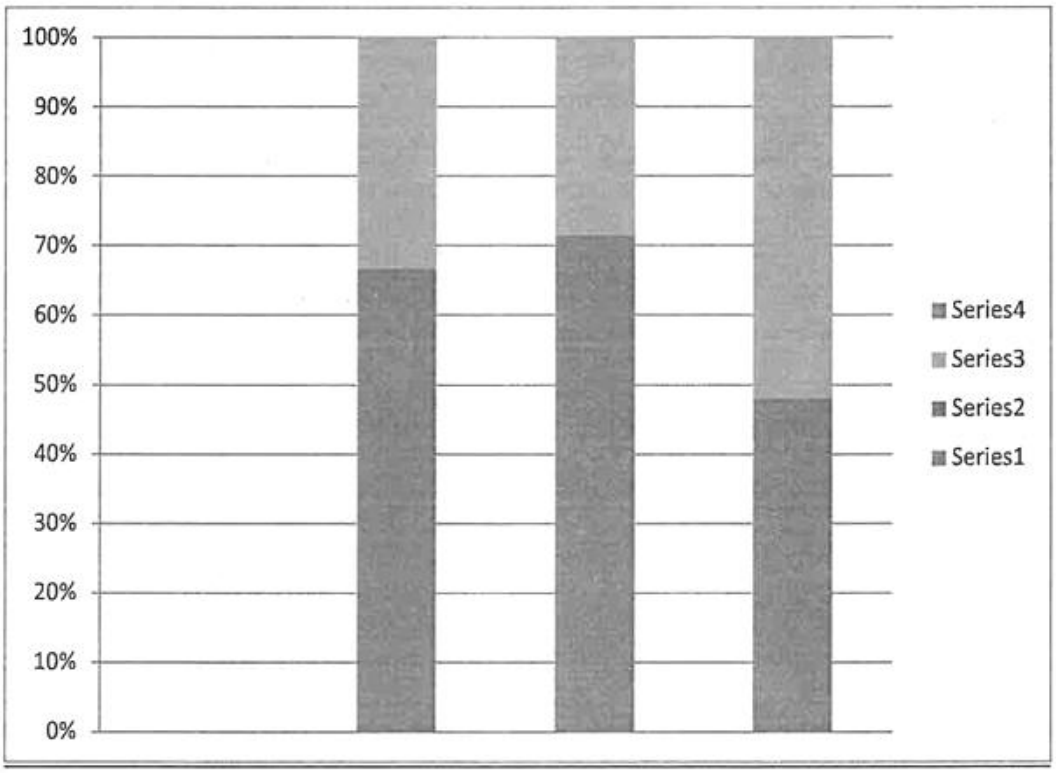


TABLE – 6; Overall Improvement of the Patient-clinically, in One month (20)

Age group	Overall Improvement in symptoms 2 weeks , 4 weeks.		% of Improvement
21-45	6	10	60 %
45-60	3	4	65 %

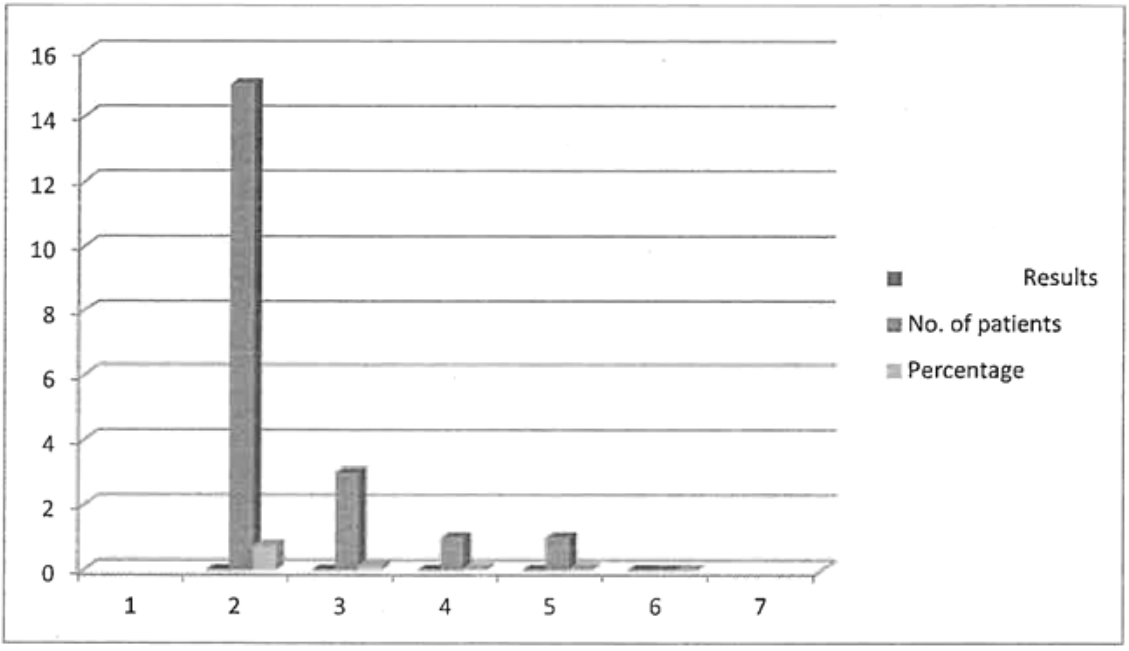


Interpretation

After the treatment of 30 days, 60% belonging to age group 25-40 years and 65% belonging to age group 41-60 years respectively had significant overall 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 of all symptoms	15	75 %
Moderate improvement	03	15 %
Mild improvement	01	5 %
No significant relief	01	5 %
Drop out	*0*	0 %



Interpretation

After the treatment of 30 days, 15 patients (75%) had very good improvement of symptoms, 3 patients (15%) had moderate improvement, 1 patient (5%) had mild improvement and 1 patient (5%) had no significant improvement from 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 trialby 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 are properly written and whether the recruiting and treatment procedures are adequately performed 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 and independent researchers will assess the progress of the clinical trial and severe adverse 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 center for Three years.

CONCLUSION:

Phase II A, Single center, Open label, therapeuticexploratory clinical trials, The current Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is designed to evaluate the efficacy of Proprietary Ayurvedic Medicine - O'STRONG LIV TABLET, Manufactured by VIJAYANI NUTRACEUTICALS PVT LTD, No.2B/1,2B/2, 6th street, 3rd Main road, Ambattur industrial estate South, Ambattur, Chennai-600058. Tamil Nadu. on patients suffering from clinical symptoms of “Yakrutvikaara (Grade-1 Fatty liver), Kaamala (Viral Hepatitis) and Pleeharoha (Alcoholic liver and spleen disease), with symptoms like Excessive tiredness, Shortness of breath, Loss of appetite, Nausea, Pain in the abdomen, fatigue, bloating of abdomen” etc.

By consolidating the results obtained in the clinical investigations and laboratory investigations, it is hereby concluded that the Proprietary Ayurvedic Medicine – 0RIEN’S

STRONG LIV TABLET, is highly effective in controlling Clinical symptoms of "Yakrutvikaara (Grade-1 Fatty liver), Kaamala (Viral Hepatitis and Pleeharoha (Alcoholic liver and spleen disease), with symptoms like Excessive tiredness, Shortness of breath, Loss of appetite, Nausea, Pain in the abdomen, fatigue, bloating of abdomen" etc. It also contributed for their enhanced Liver health at baseline and at the completion of treatment, in the recruited patients.

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