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ORIGINAL ARTICLE

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

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ABSTRACT

Background of the study: Type II Diabetes Mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance, persistent hyperglycemia, and associated complications such as polyuria, polydipsia, polyphagia, and diabetic neuropathy. Conventional treatments include pharmacological agents like metformin, insulin, and SGLT-2 inhibitors, but these may have side effects and long-term dependency risks. Ayurveda offers a natural and holistic approach to diabetes management, focusing on herbal formulations that regulate blood glucose levels while minimizing complications. DIACARE CAPSULE, a proprietary Ayurvedic medicine, has been developed to support glycemic control and overall metabolic balance. The primary objective of this study was to clinically validate the efficacy of DIACARE CAPSULE in managing diabetes-related symptoms and improving glycemic control. The study aimed to assess its impact on blood glucose levels, metabolic health, and overall patient well-being. **Methods:** This Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial was conducted on 20 patients diagnosed with T2DM. Participants were administered 1-2 DIACARE CAPSULES twice daily with lukewarm water for 30 days. Clinical and laboratory assessments were performed at baseline (day-1) and post-treatment (day-30). Ethical approval was obtained, and written informed consent was secured from all participants. **Results:** After 30 days of treatment: 80% (16 patients) experienced significant symptom improvement. 10% (2 patients) showed moderate improvement. 5% (1 patient) had mild improvement. 5% (1 patient) dropped out of the study. Laboratory investigations confirmed improvements in blood sugar levels and metabolic parameters. No severe adverse effects were reported. **Conclusion:** DIACARE CAPSULE demonstrated significant efficacy in managing diabetes-related symptoms and improving glycemic control. The findings support its potential as a safe and effective Ayurvedic intervention for T2DM. Further large-scale studies are recommended for validation.

Keywords: Obesity, Hypercholesterolemia, Metabolic disorders, Ayurvedic medicine

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INTRODUCTION

Diabetes mellitus, particularly Type II Diabetes Mellitus (T2DM), is a chronic metabolic disorder characterized by persistent hyperglycemia due to insulin resistance, pancreatic β-cell dysfunction, or a combination of both[1]. T2DM has become a global epidemic, with the International Diabetes Federation (IDF) estimating that 537 million adults worldwide were living with diabetes in 2021, a number projected to rise to 783 million by 2045[2]. This increasing prevalence is primarily attributed to sedentary lifestyles, poor dietary habits, obesity, and genetic predisposition[3].

Pathophysiology and Complications of Type II Diabetes: T2DM develops when insulin resistance in peripheral tissues leads to inadequate glucose uptake, forcing pancreatic β-cells to produce more insulin to compensate[4]. Over time, this compensatory mechanism fails, resulting in chronic hyperglycemia and metabolic dysfunction[5]. The condition is often associated with systemic inflammation, oxidative stress, and endothelial dysfunction, all of which contribute to long-term complications such as cardiovascular disease, nephropathy, retinopathy, and neuropathy[6].

The classical symptoms of diabetes include polyuria (excessive urination), polydipsia (excessive thirst), and polyphagia (excessive hunger), collectively known as the "three P's" of diabetes[7]. Additionally, many patients experience fatigue, slow wound healing, recurrent infections, and weight fluctuations. Diabetic neuropathy, a common complication, results in nerve damage that causes tingling, numbness, and pain in the extremities, significantly affecting the quality of life[8].

Limitations of Conventional Diabetes Treatments: Conventional treatment strategies for T2DM focus on maintaining glycemic control through pharmacological and lifestyle interventions[9]. The first-line medication for T2DM is metformin, which reduces hepatic glucose production and improves insulin sensitivity[10]. Other drug classes, such as sulfonylureas, DPP-4 inhibitors, SGLT-2 inhibitors, and GLP-1 receptor agonists, target different aspects of glucose metabolism. Long-term use of sulfonylureas may lead to hypoglycemia and weight gain, while SGLT-2 inhibitors increase the risk of urinary tract infections. Insulin therapy, though effective, requires strict monitoring and is often associated with weight gain and increased risk of hypoglycemia.

Lifestyle interventions, including dietary modifications and regular physical activity, are essential in diabetes management, but adherence remains a challenge due to socio-behavioral factors. Moreover, despite advancements in diabetes care, many patients struggle to achieve and maintain optimal glycemic control, highlighting the need for complementary and alternative therapies.

Ayurveda and Its Role in Diabetes Management: Ayurveda, the traditional system of medicine practiced in India for over 5,000 years, offers a holistic approach to managing metabolic disorders like diabetes (Madhumeha)[16]. Ayurvedic treatments focus on balancing bodily functions through herbal formulations, dietary modifications, and lifestyle interventions. Several Ayurvedic herbs have demonstrated hypoglycemic effects, making them valuable additions to conventional diabetes care.

Notable anti-diabetic Ayurvedic herbs include: Gymnema sylvestre (Gurmar) – Known as the "sugar destroyer," it reduces sugar cravings, enhances insulin secretion, and improves glucose uptake by cells. Tinospora cordifolia (Guduchi) – Exhibits antioxidant and anti-inflammatory properties, helping to reduce insulin resistance. Momordica charantia (Bitter melon) – Contains bioactive compounds that mimic insulin and promote glucose uptake. Withania somnifera (Ashwagandha) – Enhances pancreatic β-cell function and improves glucose metabolism. Berberis aristata (Daruharidra) – Shown to improve lipid and glucose metabolism, reducing systemic inflammation. The combination of these herbs in Ayurvedic formulations provides multi-targeted benefits, making them promising alternatives or adjuncts to conventional diabetes treatments.

DIACARE CAPSULE: An Ayurvedic Solution for Diabetes Management: DIACARE CAPSULE is a proprietary Ayurvedic formulation designed to regulate blood sugar levels and improve metabolic balance. The formulation includes a blend of anti-diabetic herbs that work synergistically to enhance insulin function, reduce glucose absorption, and mitigate oxidative stress.

One of the key ingredients in DIACARE CAPSULE is Gymnema sylvestre, which has been shown to increase insulin secretion, promote pancreatic regeneration, and reduce postprandial glucose spikes. Clinical studies indicate that Gymnema supplementation improves glycemic control in T2DM patients while reducing dependency on conventional medications. Another essential component is Berberis aristata, which contains berberine, a compound that enhances glucose metabolism and reduces insulin resistance. Research suggests that berberine is as effective as metformin in lowering blood sugar levels without causing significant side effects. Trigonella foenum-graecum (Fenugreek) is also included in DIACARE CAPSULE for its ability to slow carbohydrate digestion and absorption, resulting in better postprandial glucose control. Additionally, Curcuma longa (Turmeric) acts as a potent anti-inflammatory and antioxidant agent, protecting pancreatic β-cells from oxidative damage.

Scientific Validation and Need for Clinical Trials: Despite the growing acceptance of Ayurvedic medicine in diabetes management, scientific validation through clinical trials is crucial for its integration into modern healthcare. Many Ayurvedic formulations lack standardized dosages and robust clinical evidence, making it essential to conduct controlled trials to evaluate their efficacy and safety. This study aims to bridge the gap between traditional knowledge and scientific research by clinically validating the efficacy of DIACARE CAPSULE in managing T2DM.

Objective of the Study: The primary objective of this study is to evaluate the efficacy of DIACARE CAPSULE in reducing diabetes-related symptoms, including polyuria, polydipsia, polyphagia, and diabetic neuropathy. The study also aims to assess its impact on blood sugar levels, metabolic markers, and patient-reported outcomes over a 30-day treatment period. By providing evidence-based support for DIACARE CAPSULE. If successful, the findings could contribute to the broader acceptance of Ayurvedic medicine in mainstream healthcare, offering a natural, side-effect-free alternative to conventional diabetes treatments.

METHODOLOGY:

Screening of Patients for study:

In the present study, patients suffering from symptoms like "Polyurea, Polydipsia and Polyphagia" in Madhumeha vyadhi (Compared to Type II Diabetes mellitus)" 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 "Polyurea, Polydipsia and Polyphagia" in Madhumeha vyadhi (Compared to Type II Diabetes mellitus)" 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 Fiistory and physical examination of the patients along with Envagai thaervu, tridosha naadi, saptha dhatu thaervu etc. were recorded in a case sheet on first day. The second Clinical assessment were 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 Proprietary Ayurvedic Medicine — DIACARE CAPSULE, 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 that 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:

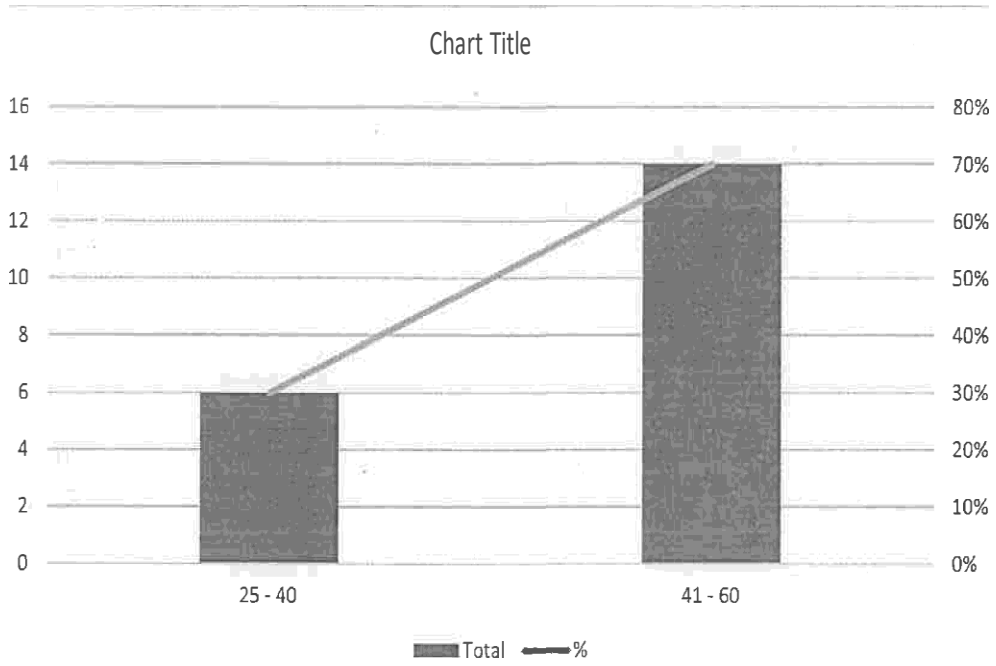
Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory. 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
CLINICAL CHEMISTRY					
Serum/Plasma	Glucose(Fasting)	GOD-POD		mg/dl	70-110
Serum/Plasma	Glucose(PP)	GOD-POD		mg/dl	100-140
Serum/Plasma	Creatinine	Kinetic		mg/dl	0.6-1.4
Blood	Differential count(DC)	VESMATIC			
	Neutrophils			%	40-80
	Lymphocytes			%	20-40
	Eosinophils			%	01-06
	ESR			mm/hr	0-10
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
CLINICAL PATHOLOGY URINE COMPLETE					
Urine	Protein	Combur UX strip (ROCHE)		..	
Urine	Ketone			..	
Urine	Pus cells			..	/Hpf
Urine	Epithelial cells			..	/Hpf
Serum	HbA1c	Sysmex XS 8 i		%	Normal ;Below 6.0 Prediabetic ;6.0-6.4 Diabetic ;6.5 and above

Discussion and Statistical analysis of the Results Obtained

TABLE -1.1 ; Age group of Patients (20)

Age group	Total	%
2S-40	06	30%
41-60	14	70%



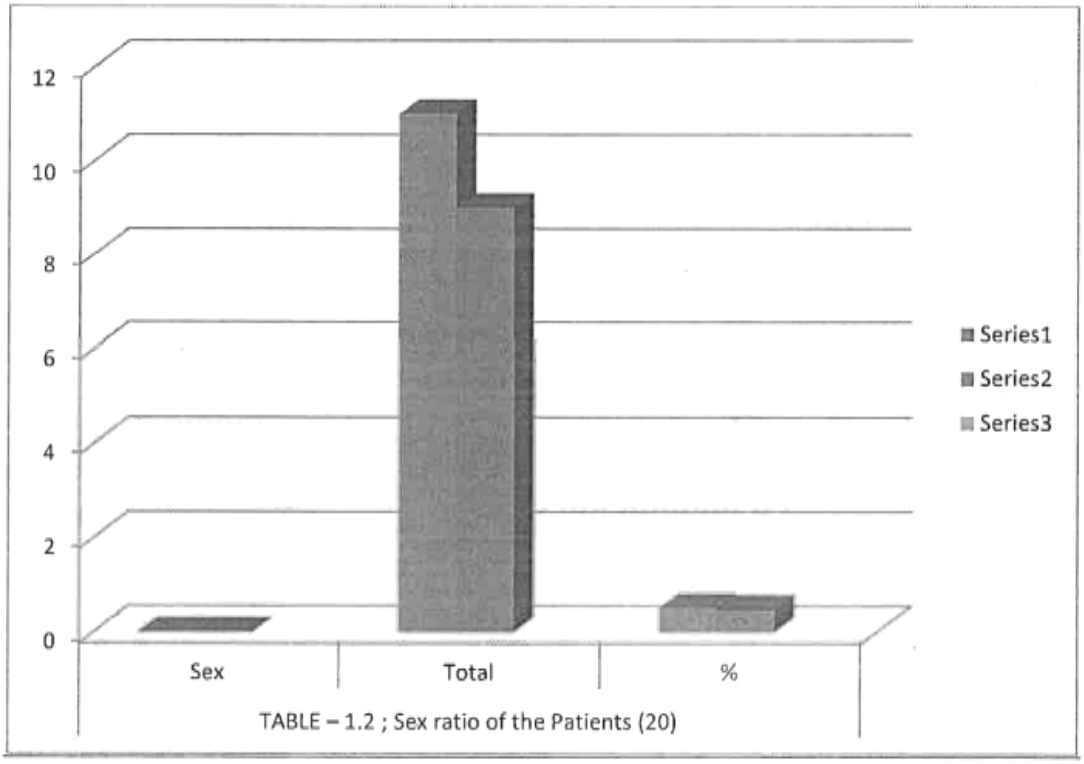
Interpretation

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

taken for study.

TABLE – 1.2; Sex ratio of the Patients (20)

Sex	Total	%
Male	11	52%
Female	09	48%

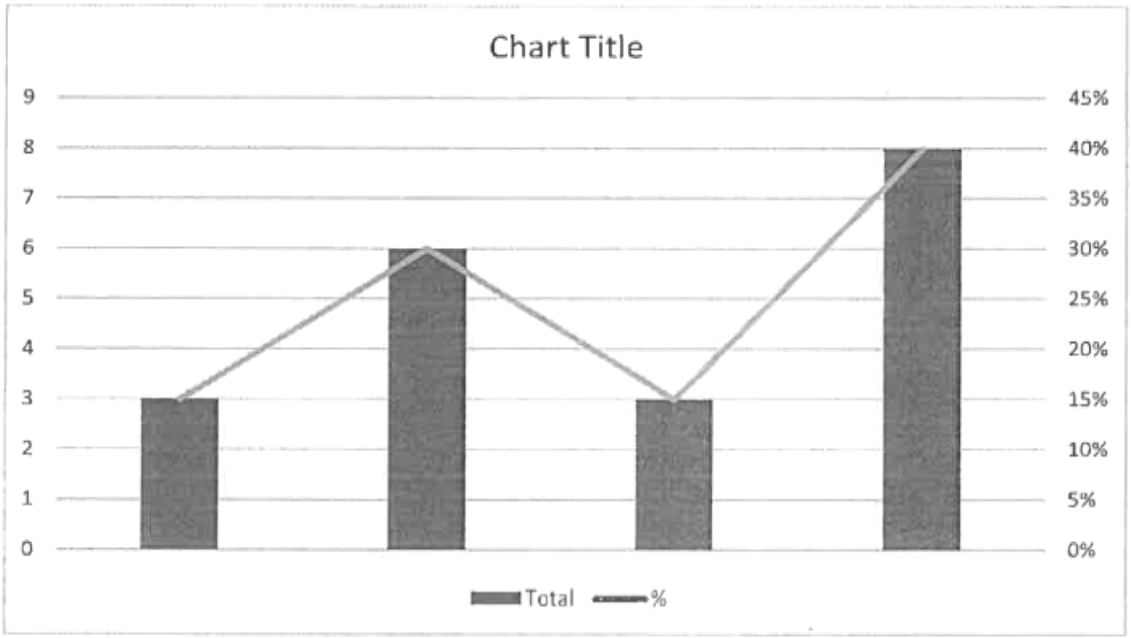


Interpretation

In total, 11 patients belonging to Male sex and 9 patients belonging to female sex respectively had been taken for study.

TABLE – 1.3; Chronicity of the Disease (20)

Onset		Total	%
Acute onset (within 3 months)	21-30 years	3	15%
	31-40 years	6	30%
Chronic onset (more than 3 months)	21-30 years	3	15%
	31-40 years	8	40%

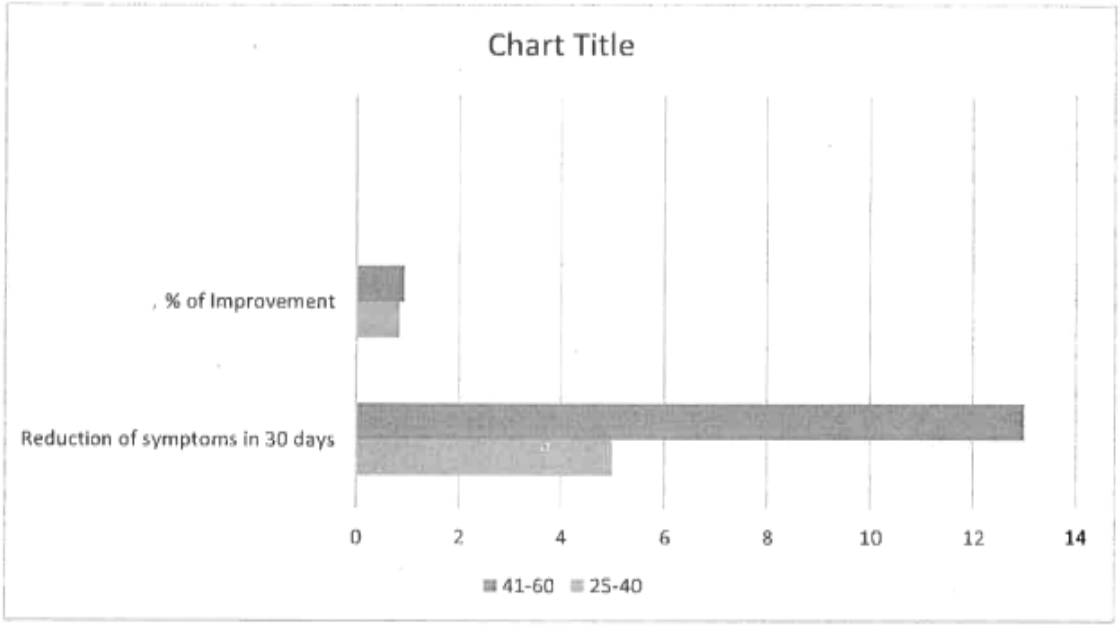


Interpretation

In total, 6 patients belonging to age group 25-40 years and 14 patients belonging to age group 41-60 years respectively who had been taken for study had the symptoms from within 3 months and more than 3 months.

TABLE – 1.4; Reduction of Excessive tiredness and fatigue clinically- in One month (20)

Age group	Reduction of symptoms in 30 days	% of Improvement
25-40	5	83.3%
41-60	13	92.8 %

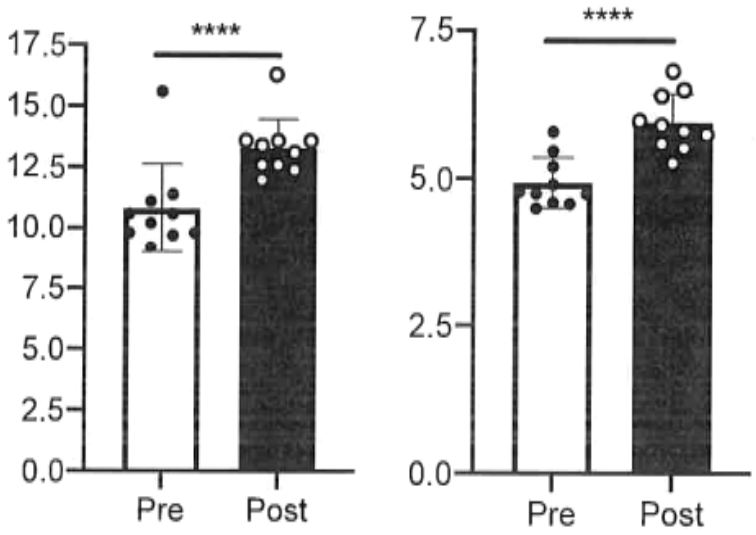


Interpretation

After the treatment of 30 days, 5 patients belonging to age group 25-40 years and 13 patients 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



IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS

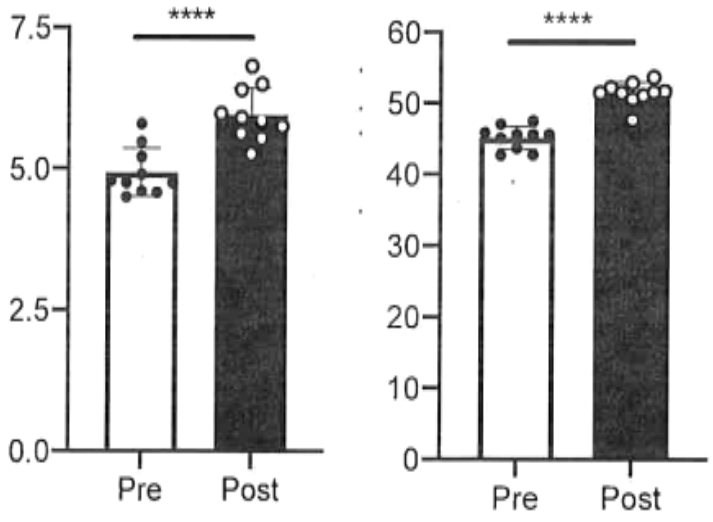
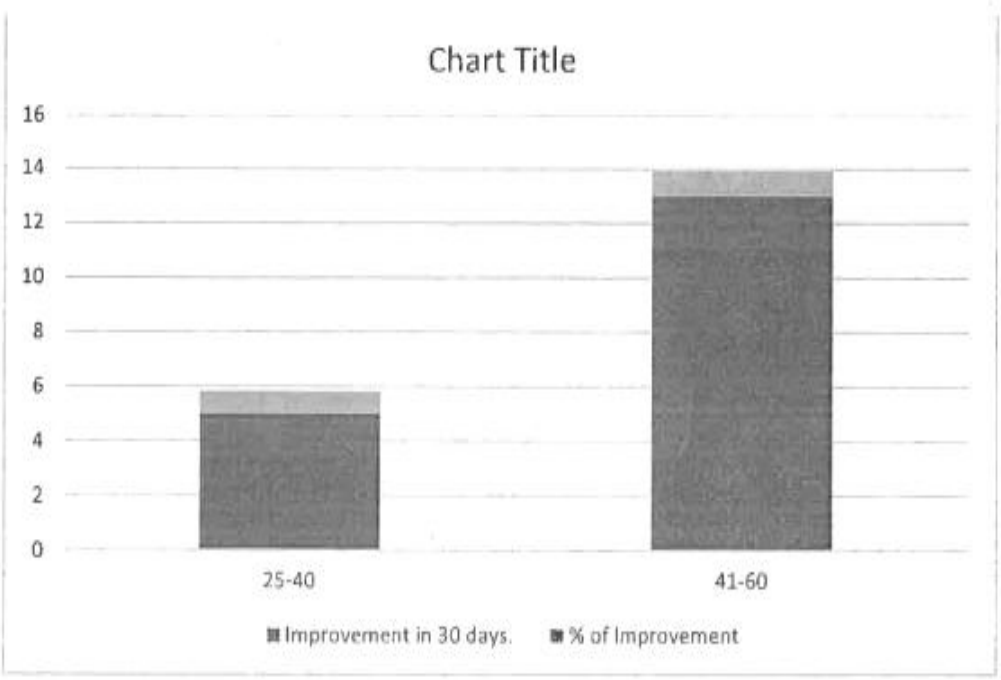


TABLE – 1.5; Improvement of Polyurea clinically- in One month (20)

Age group	Improvement in 30 days.	% of Improvement
25-40	5	83.3%
41-60	13	92.8 %

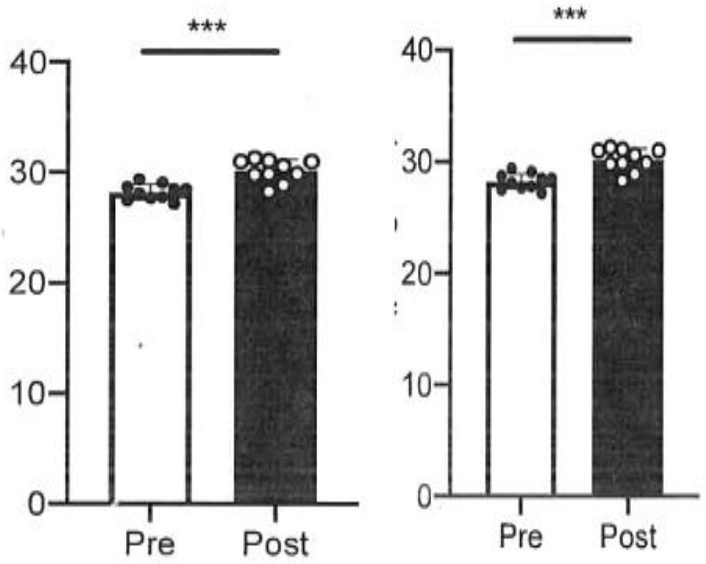


Interpretation

After the treatment of 30 days, 5 patients belonging to age group 25-40 years and 13 patients belonging to age group 41-60 years respectively had significant improvement of Polyurea.

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS

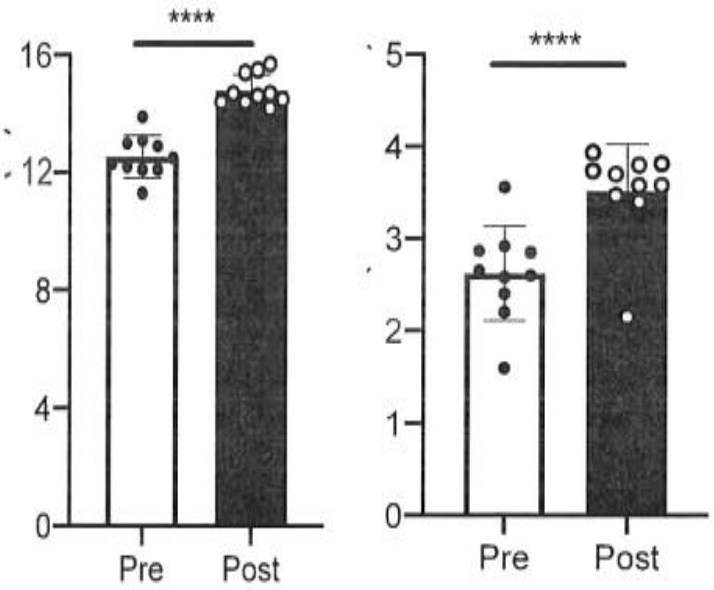
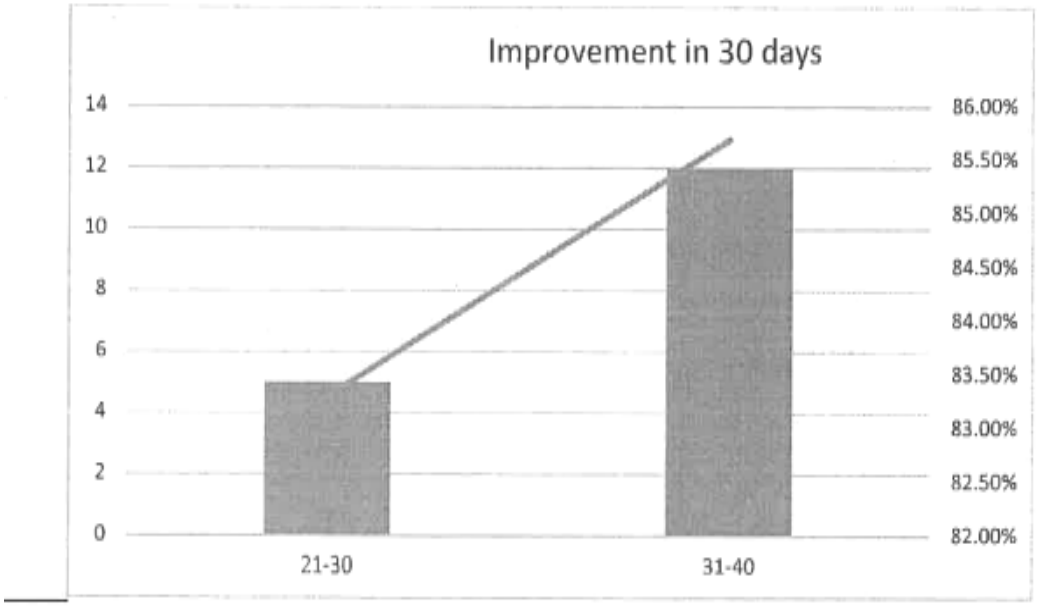


TABLE – 1.6; Improvement in Excessive appetite - Polyphagia in One month (20)

Age group	Improvement in 30 days.	% of Improvement
25-40	5	83.3 %
41-60	12	85.7 %

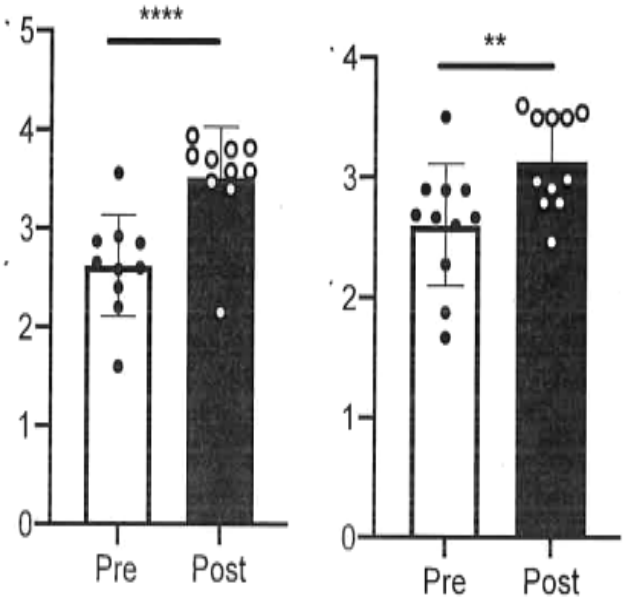


Interpretation

After the treatment of 30 days, 5 patients belonging to age group 25-40 years and 12 patients belonging to age group 41-60 years respectively had significant improvement of Excessive appetite - Polyphagia.

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



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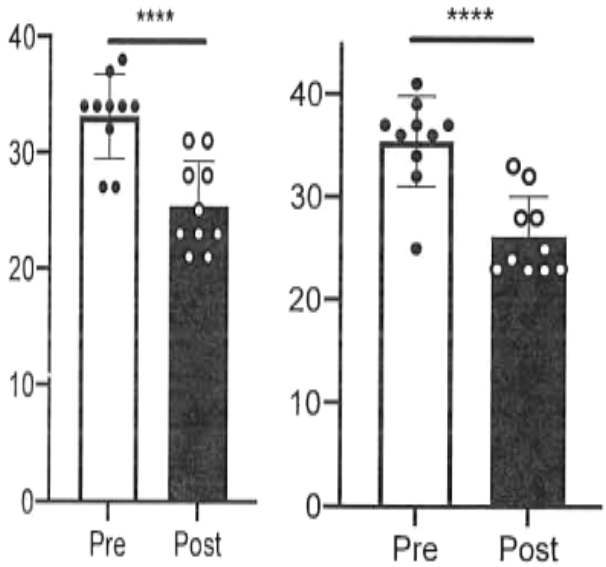
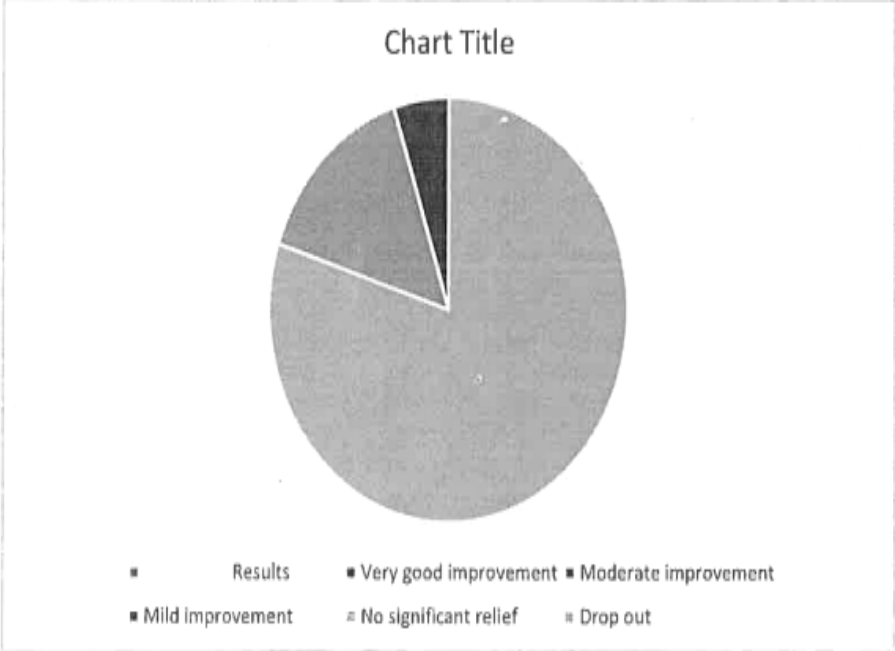


Table – 1.7; Overall results of Treatment in reduction of Clinical symptoms and Laboratory investigations in patients treated (Total 20 patients)

Results	No. of patients	Percentage
Very good improvement	16	80 %
Moderate improvement	02	10 %
Mild improvement	01	5 %
No significant relief	0	0 %
Drop out	01	5 %

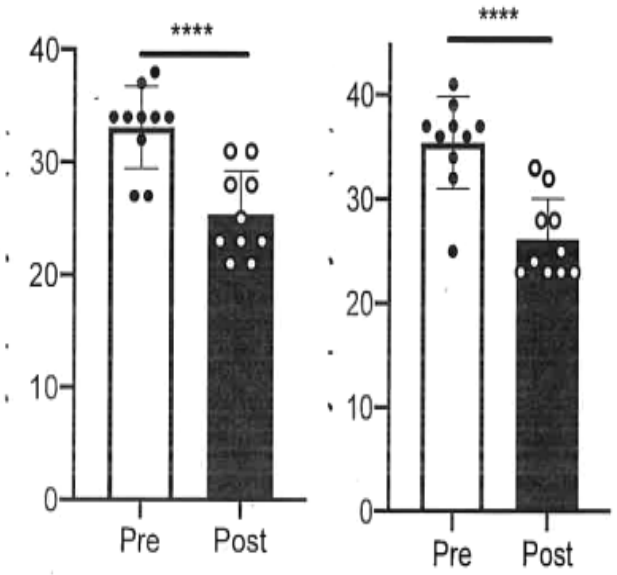


Interpretation

After the treatment of 30 days, 16 patients (80%) had very good improvement of symptoms, 2 patients (10%) had moderate improvement, 1 patient (05%) had mild improvement and there was one (05%) dropout from the study.

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



IMPROVEMENT IN LABORATORY FINDINGS

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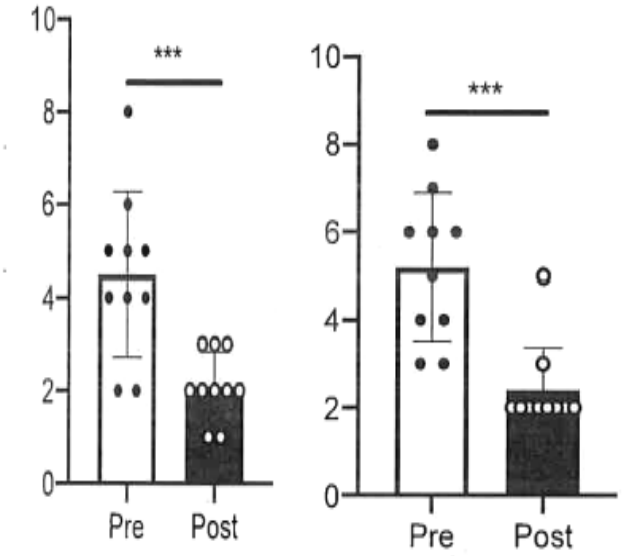
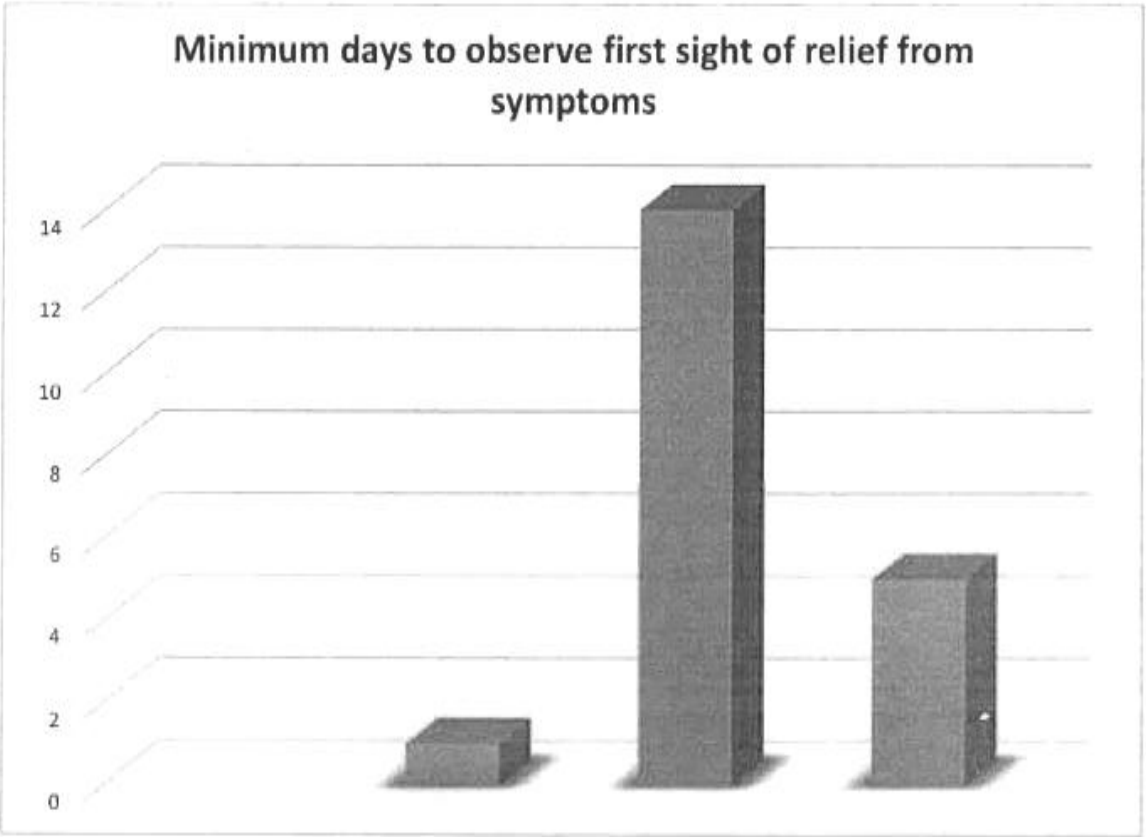
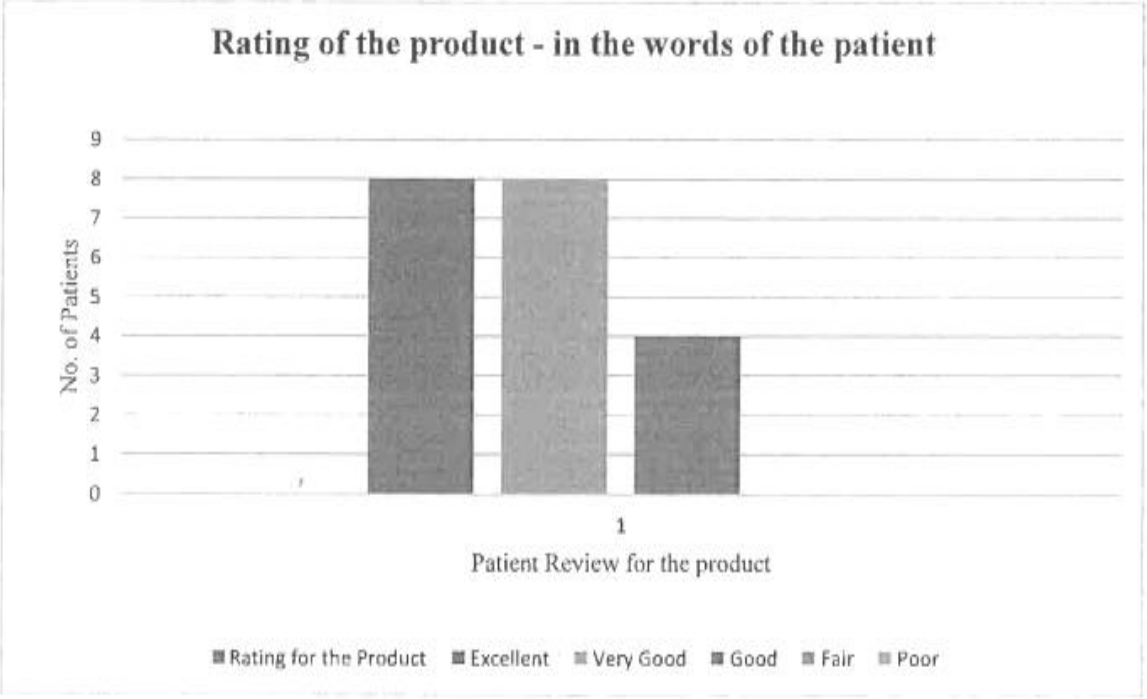


Table-1 ; Number of days to observe Initial relief from Polyurea, Polydipsia and Polyphagia .

S. no	Unique.ID	Age/sex	Date of issue of medicine	Date of first sight of relief observed	Number of days required for first sight of relief
1	5223	65/M	05.12.24	20.12.24	15
2.	5425	50/M	05.12.24	25.12.24	20
3.	5294	58/M	05.12.24	22.12.22	17
4.	6404	46/F	05.12.24	05.01.24	30
5.	4120	55/M	05.12.24	01.01.25	25
6.	5296	46/F	05.12.24	21.12.24	16
7.	6517	49/F	06.12.24	06.01.25	30
8.	5592	65/F	06.12.24	21.12.24	15
9.	4731	62/F	06.12.24	29.12.24	23
10.	3859	64/F	06.12.24	06.01.25	30
11.	4085	51/M	06.12.24	23.12.24	17
12.	5567	62/M	06.12.24	30.12.22	24
13.	6670	39/F	07.12.24	31.12.24	24
14.	4835	46/M	07.12.24	26.12.24	19
15.	5943	60/M	07.12.24	01.01.25	25
16.	4112	67/F	07.12.24	23.12.24	16
17.	6550	38/M	07.12.24	31.12.24	24
18.	5709	37/F	08.12.24	05.01.25	27
19.	5753	44/M	08.12.24	03.01.25	25
20.	4810	68/M	08.12.24	02.01.25	24


Minimum days to observe first sight of relief from symptoms
14
12
10
8
6
4
2
0


Rating of the product - in the words of the patient
No. of Patients
9
8
7
6
5
4
3
2
1
0
1
Patient Review for the product
Rating for the Product
Excellent
Very Good
Good
Fair
Poor

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 table 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 are properly written and whether the recruiting and treatment procedures are adequately performed acc-ording 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.

CONCLUSION

The current Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is designed to evaluate the efficacy of Proprietary Ayurvedic Medicine - DIACARE CAPSULE, Manufactured by VIJAYANI NUTRACEUTICALS PVT 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 “Polyurea, Polydipsia and Polyphagia” in Madhumeha vyadhi (Compared to Type II Diabetes mellitus)“.

By consolidating the results obtained in the clinical investigations and laboratory investigations, it is hereby concluded that the Proprietary Ayurvedic Medicine - DIACARE CAPSULE, is highly effective in controlling Clinical symptoms of “Polyurea, Polydipsia and Polyphagia” in Madhumeha vyadhi (Compared to Type II Diabetes mellitus)” in the recruited

patients. It also helped in reducing the diabetic complications like Diabetic neuropathy.

REFERENCES

1. WHO. Obesity and overweight. World Saeedi P, et al. Global and regional diabetes prevalence estimates. Diabetes Res Clin Pract. 2019; 157:107843.
2. IDF Diabetes Atlas, 10th Edition. International Diabetes Federation; 2021.
3. Harding JL, et al. Global trends in diabetes complications. N Engl J Med. 2019; 381(8):748-758.
4. DeFronzo RA, et al. Pathophysiology of Type 2 Diabetes Mellitus. Nat Rev Endocrinol. 2021; 17(2):63-72.
5. Olefsky JM, Glass CK. Macrophages, inflammation, and insulin resistance. Annu Rev Physiol. 2019; 82:153-172.
6. Tripathi BK, Srivastava AK. Diabetes and herbal medicines. Curr Diabetes Rev. 2021; 17(1):45-53.
7. Cusi K. Insulin resistance and diabetes. J Clin Invest. 2020; 130(1):9-18.
8. Lin X, et al. Global burden of diabetes. Diabetes Care. 2020; 43(5):767-775.
9. Cefalu WT, et al. Diabetes management strategies. Diabetes Care. 2019; 42(1):1770-1800.
10. Kushner RF, Ryan DH. Treatment strategies for obesity. J Clin Invest. 2016; 127(1):87-94.

S. Suman, P. Karthikeyan, S. Moulishankar, et.al (2025). Open Label Single Centric Clinical Exploratory Of Efficacy Study On Diacare Capsule, An Ayurvedic Proprietary Formulation, ijmaes; 11(1); 2063-2082.