International
Journal of Medical and Exercise Science
(Multidisciplinary, Peer Reviewed and Indexed Journal)

ORIGINAL ARTICLE

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

Search engine:
www.ijmaes.org

S. Suman[1], P. Karthikeyan[2], S. Moulishankar[3], S. Sridhar [4], G. Raaja[5]*, G.S. Aathithiah[6],M. Vetriselvan[7], Joemon[8], R. Pachiyappan[9], B. Devendran[10]

Authors:
[1]Managing Director, Vijayani Nutraceuticals Pvt Ltd, [2]Director, Vijayani Nutraceuticals Pvt Ltd, [3]Director, Vijayani Nutraceuticals Pvt Lt, [4]Principal Research Investigator, Ashram Siddha Research Institute, [5]Medical Officer, Vijayani Nutraceuticals Pvt Ltd, [6]Medical Officer, Vijayani Nutraceuticals Pvt Ltd, [7]General Manager, Vijayani Nutraceuticals Pvt Ltd, [8]Manufacturing Incharge, Vijayani Nutraceuticals Pvt Ltd, [9]Product Development, Oriens Global Marketing Pvt Ltd, [10]Pharmacologist, Vijayani Nutraceuticals Pvt Ltd.

Corresponding Author:
*Dr. G. Raaja, Medical Officer, Vijayani Nutraceuticals Pvt. Ltd., Chennai, Tamil Nadu, India.
Email ID: raaja.ayurdoctor@gmail.com

ABSTRACT

Introduction: Reproductive health and vitality decline with age, stress, and poor lifestyle choices, leading to conditions such as Sukrasthambana (sexual debility), Dhathuksheena (oligospermia), and Dourbalya (nervous weakness). Symptoms like fatigue, stress, loss of libido, and erectile dysfunction impact overall well-being and quality of life. Conventional treatments, including hormone therapy and synthetic aphrodisiacs, often lead to dependency and adverse effects. Ayurvedic medicine offers a holistic and natural approach to enhancing reproductive health, vitality, and stamina. This study clinically validates Shilajit Capsule, a proprietary Ayurvedic formulation, for its efficacy in improving sexual health, energy levels, and mental well-being. The primary objective of this Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial was to assess the efficacy and safety of Shilajit Capsule in improving reproductive health, reducing stress, and enhancing stamina. **Methods:** A total of 20 male patients suffering from sexual debility and associated 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 energy levels, libido, erectile function, anxiety reduction, and overall reproductive health were monitored. **Results:** At the end of 30 days, 75% (15 patients) exhibited very good improvement, 15% (3 patients) showed moderate improvement, and 10% (2 patients) had mild improvement. The formulation significantly enhanced mental calmness, reduced anxiety, and improved reproductive health. No adverse effects were reported. **Conclusion:** The study confirms that Shilajit Capsule is a potent Ayurvedic intervention for enhancing sexual wellness, vitality, and energy levels. The formulation demonstrated significant improvements in reproductive health, stress reduction, and stamina, making it a promising natural alternative. Further large-scale trials are recommended for broader validation.

Keywords: Sukrasthambana, Dhathuksheena, Dourbalya, Erectile dysfunction

Received on 29th January 2025; Revised on 18th February 2025; Accepted on 28th February 2025
DOI:10.36678/IJMAES.2025.V11I01.008

INTRODUCTION

Sexual health and overall vitality play a crucial role in an individual's physical, mental, and emotional well-being. Factors such as age, stress, poor diet, lack of physical activity, chronic illnesses, and environmental toxins contribute to sexual dysfunction, low libido, oligospermia (low sperm count), and erectile dysfunction[1]. These conditions not only affect reproductive health but also lead to mental distress, anxiety, and reduced quality of life[2]. In modern medicine, conventional treatments like testosterone replacement therapy, phosphodiesterase-5 (PDE5) inhibitors (e.g., sildenafil), and synthetic aphrodisiacs are commonly prescribed[3]. However, these treatments often have adverse effects such as dependency, cardiovascular risks, hormonal imbalances, and psychological side effects[4].

Given the limitations of modern therapies, Ayurvedic medicine offers a holistic and natural approach to improving sexual health, stamina, and mental well-being. Ayurveda considers sexual debility (Klaibya), premature ejaculation (Shukraghata Vata), and low sperm count (Shukradushti) as conditions caused by **imbalances in the three Doshas (Vata, Pitta, and Kapha), weak Agni (digestive fire), and accumulation of toxins (Ama)**[5]. Rejuvenating therapies (Rasayana Chikitsa) and aphrodisiac formulations (Vajikarana Rasayana) are traditionally used to strengthen reproductive tissues (Shukra Dhatu), boost vitality (Ojas), and enhance overall stamina[6].

Role of Shilajit in Ayurvedic Medicine

Among the various Ayurvedic Rasayana formulations, Shilajit has been revered for centuries as a potent adaptogen, rejuvenator, and aphrodisiac. It is a herbo-mineral exudate obtained from Himalayan rocks, rich in fulvic acid, dibenzo-α-pyrones, trace minerals, and bioactive compounds[7]. In classical texts like the Charaka Samhita and Sushruta Samhita, Shilajit is described as a powerful remedy for improving strength, libido, energy, and longevity[8].

Scientific Evidence Supporting Shilajit in Male Reproductive Health

Modern research has validated the therapeutic benefits of Shilajit in enhancing sexual function, improving testosterone levels, and reducing stress-induced sexual dysfunction[9]. Studies suggest that Shilajit supplementation significantly increases sperm count, sperm motility, and serum testosterone levels in men suffering from oligospermia[10]. Additionally, it enhances mitochondrial energy production, improves nitric oxide release for better penile blood flow, and reduces oxidative stress-induced damage to reproductive cells[11].

1. Increases Testosterone & Sperm Count: Clinical trials have demonstrated that regular intake of purified Shilajit enhances total and free testosterone levels, leading to improved libido, erectile function, and reproductive potential[12].
2. Reduces Stress & Anxiety: Shilajit acts as an adaptogen, helping the body adapt to physical and mental stress. It regulates cortisol levels, which in turn helps in reducing performance anxiety and fatigue[13].
3. Enhances Mitochondrial Energy: Studies indicate that Shilajit improves ATP production in mitochondria, leading to better stamina, endurance, and muscle strength[14].
4. Improves Nitric Oxide Production: Nitric oxide is essential for relaxing blood vessels in the penile region, improving circulation, and sustaining erections. Shilajit has been

shown to increase nitric oxide synthase activity, thus enhancing erectile function[15].

5. Anti-Aging & Cellular Protection: Fulvic acid and other bioactive compounds in Shilajit possess strong antioxidant properties, preventing oxidative damage to reproductive organs and promoting cellular repair and longevity[16].

The Need for Clinical Validation of Shilajit Capsule

Although Shilajit has been used for centuries, scientific validation through clinical trials is necessary to integrate its benefits into evidence-based medicine. The present study, a Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial, was designed to evaluate the effectiveness and safety of Shilajit Capsule over a 30-day treatment period. The study aimed to assess improvements in libido, erectile function, testosterone levels, fatigue reduction, and stress management[17].

The trial recruited 20 male patients with symptoms of sexual debility, low sperm count, and fatigue. Participants were administered 1-2 capsules of Shilajit twice daily with lukewarm water. Key parameters, including libido, sperm motility, testosterone levels, energy levels, and mental well-being, were evaluated through **clinical and laboratory assessments on Day 1 (Baseline) and Day 30 (End of Trial)**[18].

With the increasing prevalence of sexual dysfunction, stress-induced fatigue, and low vitality, there is a growing need for safe, effective, and natural solutions. Shilajit Capsule, formulated with purified Shilajit, offers a promising Ayurvedic alternative for enhancing sexual wellness, stamina, and reproductive health. This clinical validation study aims to provide scientific evidence supporting the efficacy of Shilajit Capsule, helping bridge the gap between traditional Ayurvedic wisdom and modern scientific research[19].

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 “Sukrasthambana, Dhathuksheena (Oligospermia), Dourbalya (Nervous weakness) associated with Loss of libido, erectile dysfunction etc.,” 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 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 THECRO, 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 "Sukrasthambana, Dhathuksheena (OligosRermia), Dourbalya (Nervous weakness) associated with Loss of libido, erectile dysfunction 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 hosp:tal 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 40 years, suffering from clinical symptoms like

"Sukrasthambana, Dhathuksheena (Oligospermia), Dourbalya (Nervous weakness) associated with Loss of libido, erectile dysfunction etc," was taken for study.

Criteria for Exclusion:

Participants will be excluded if they are above 45 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.

Intervention:

The patients were provided with Proprietary Ayurvedic Medicine — SHILAJIT 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 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:

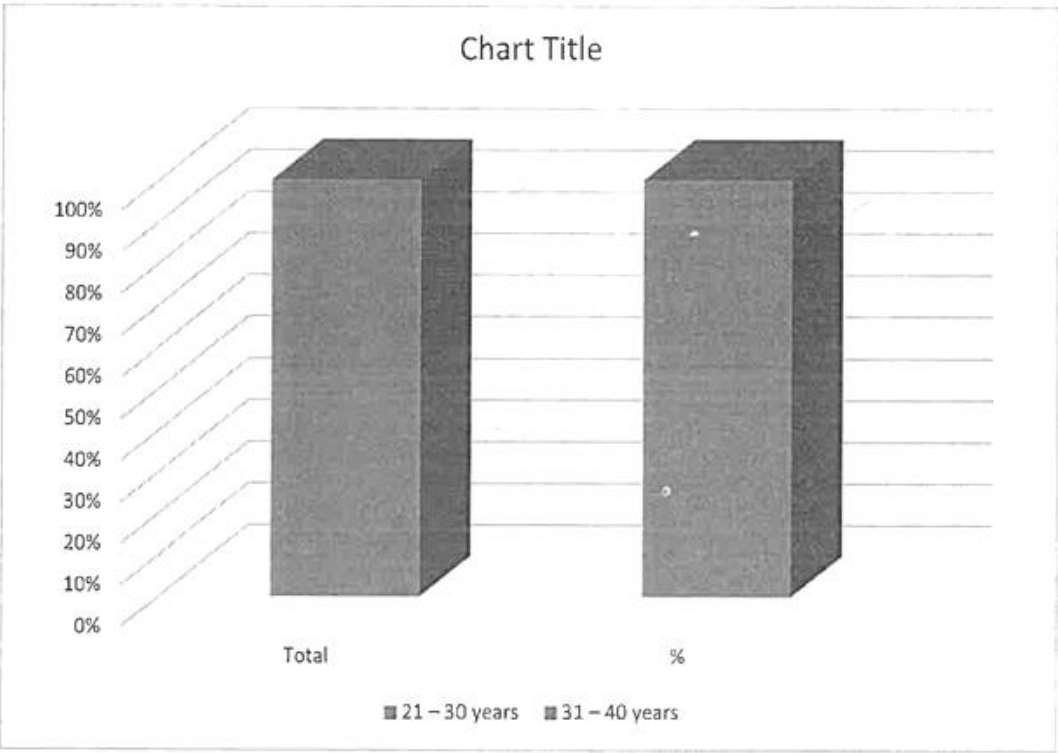
Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory. 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
CLINICAL CHEMISTRY					
Blood	Hemoglobin	Sysmex XS 8ooi		g/dl	13.0-17.0
Blood	RBC count	Sysmex XS 8ooi		mil/cu.m	4.5-6.5
Blood	17-hydroxy progesrtone	Sysmex XS 8ooi		ng/dl	100-200
Blood	Testosterone	Sysmex XS 8ooi		ng/dl	15-75
Blood	TSH	Sysmex XS 8ooi		mIU/l	0.5-5.0
Blood	Cortisol	Sysmex XS 8ooi		mcg/dl	3-10
Blood	Prolactin	Sysmex XS 8ooi		ng/mL	20-25
Blood	FSH	Sysmex XS 8ooi		mIU/mL	4.5-21.5
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
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
Serum	HbA1c	Sysmex XS 8 i		%	Normal ;Below 6.0 Prediabetic ;6.0-6.4 Diabetic ;6.5 and above
CLINICAL PATHOLOGY					
URINE COMPLETE	Glucose	Comber(Roche)			
	Protein				
	Ketone				

Discussion, Statistical Analysis & Interpretation of the Results Obtained

TABLE -1.1 ; Age group of Male Patients (20)

Age group	Total	%
21–30 years	11	55%
31–40 years	09	45%

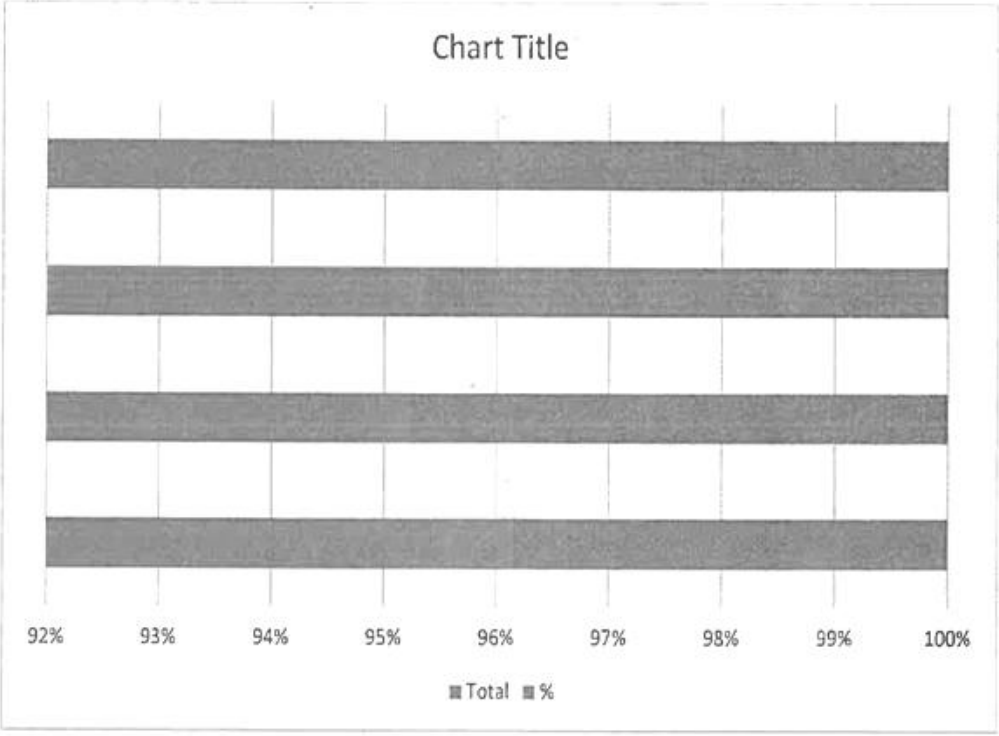


Interpretation

For the treatment of 30 days, 11male patients belong to age group 21-30 years and 9 male patients belonging to age group 31-40 years respectively were taken for study.

TABLE – 1.2; Chronicity of the Disease (20)

Onset		Total	%
Acute onset (within 3 months)	21-30 years	3	12%
	31-40 years	4	20%
Chronic onset (more than 3 months)	21-30 years	8	44%
	31-40 years	5	24%

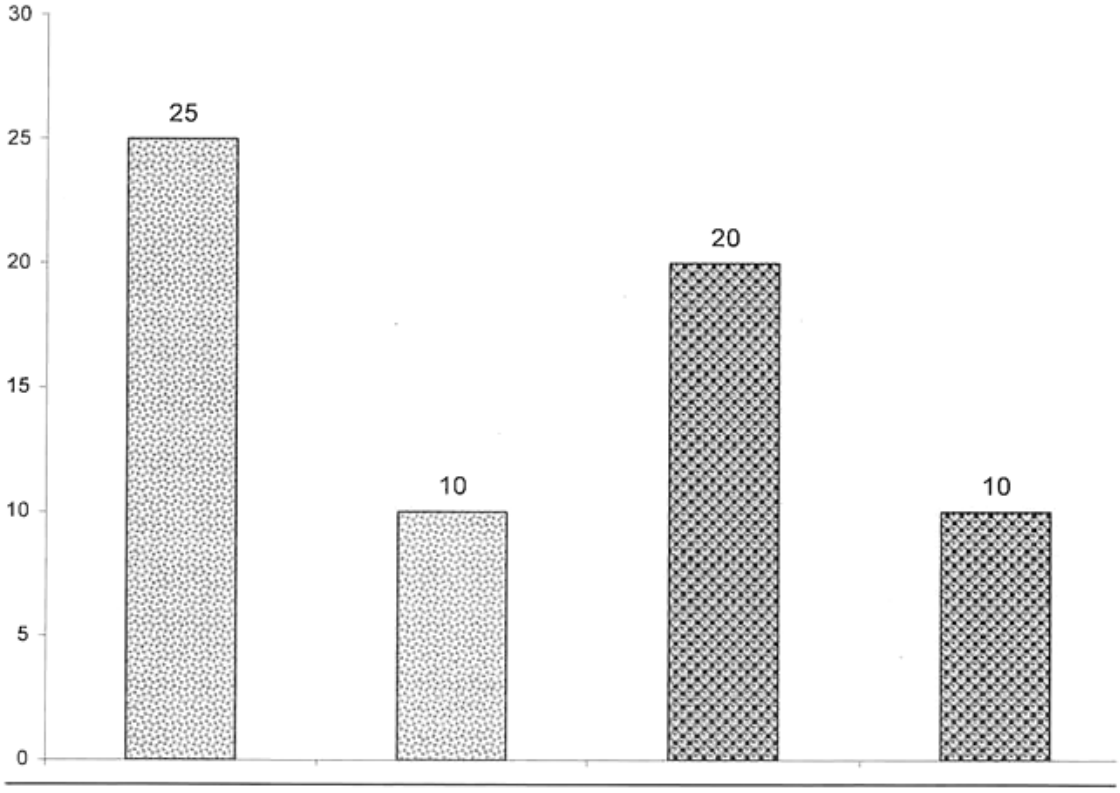


Interpretation

In total, 7 patients belonging to age group 21-30 years and 13 patients belonging to age group 31-40 years respectively who had been taken for study had the symptoms from within 3 months and more than 3 months.

TABLE – 1.3; Improvement of *Fatigue, Stress and Anxiety* in One month (20)

Age group	Improvement in Criteria Before tmt,	After tmt.	% of Improvement
21–30 years	6	5	60 %
31–40 years	5	4	50 %

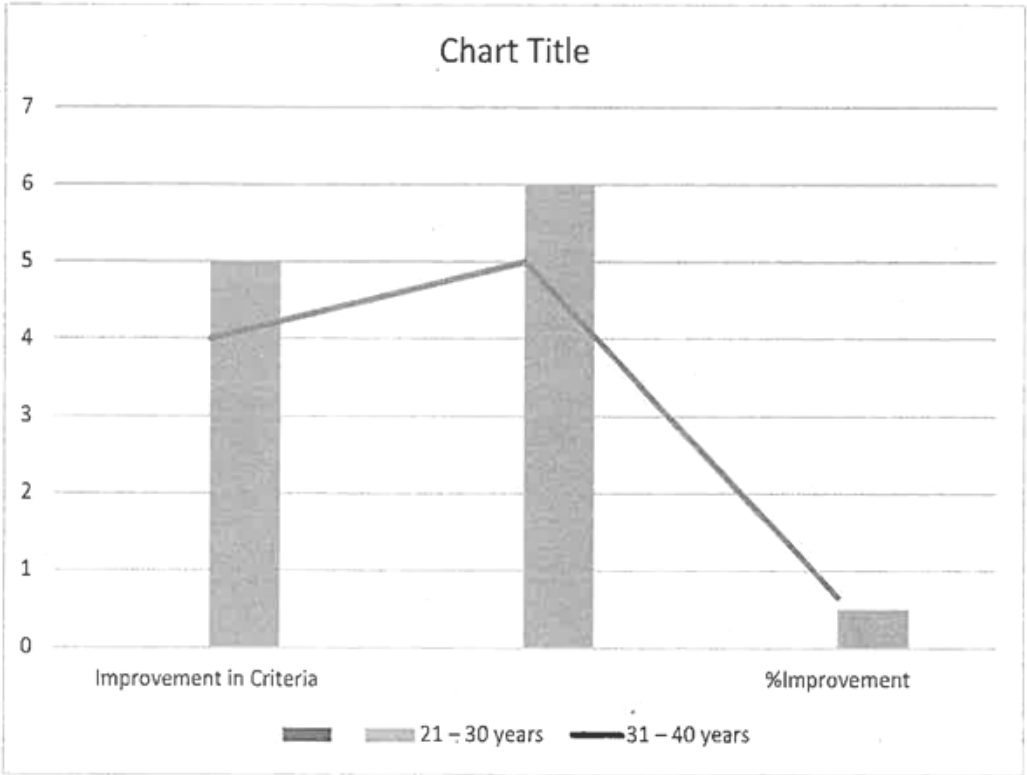


Interpretation

After the treatment of 30 days, 60% belonging to age group 21-30 years and 50% belonging to age group 31-40 years respectively had significant improvement of *symptoms.*

TABLE – 1.4; Improvement of *General well being, Vigor and Vitality* in One month (20)

Age group	Improvement in Criteria Before tmt,	After tmt.	%Improvement
21–30 years	5	6	50 %
31–40 years	4	5	66.6 %

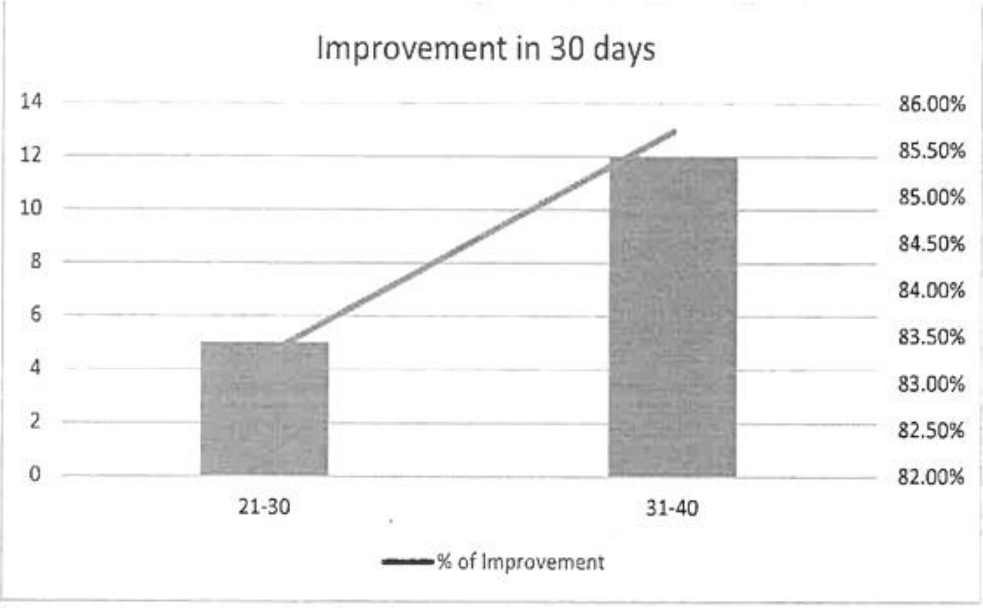


Interpretation

After the treatment of 30 days, 50% belonging to age group 21-30 years and 67% belonging to age group 31-40 years respectively had significant improvement of symptoms.

TABLE – 1.5; Improvement of *Nervous weakness and Mental calmness* in 1 month (20)

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

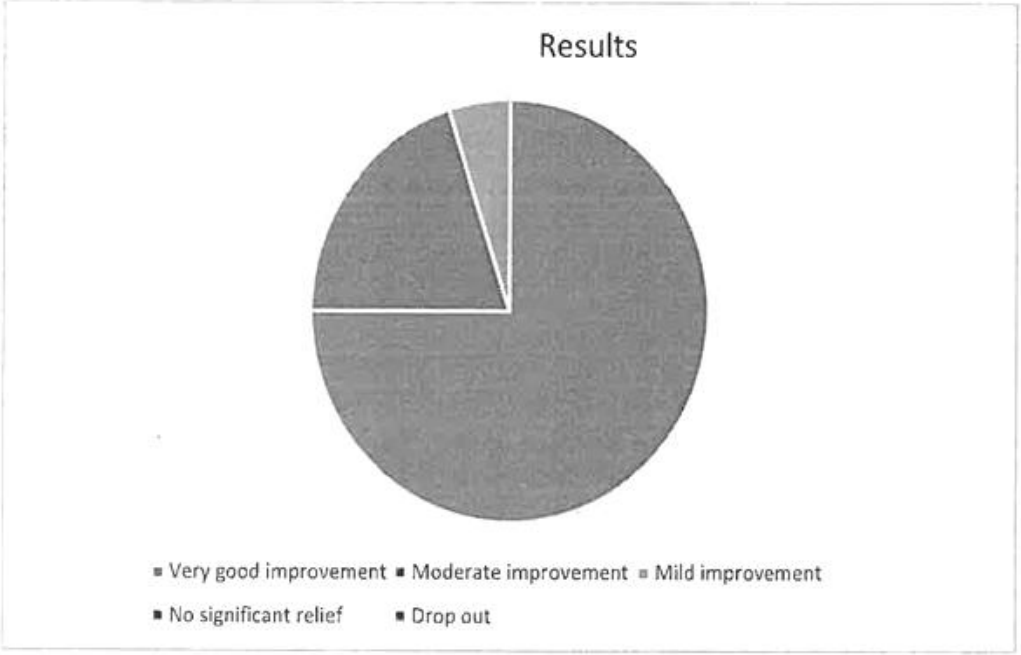


Interpretation

After the treatment of 30 days, 83% belonging to age group 21-30 years and 86% belonging to age group 31-40 years respectively had significant improvement of Nervous weakness and Mental calmness.

Table – 1.6; 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	15	75 %
Moderate improvement	03	15 %
Mild improvement	02	10 %
No significant relief	0	0 %
Drop out	0	0 %

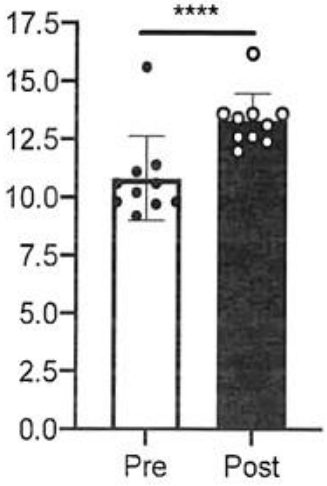


Interpretation

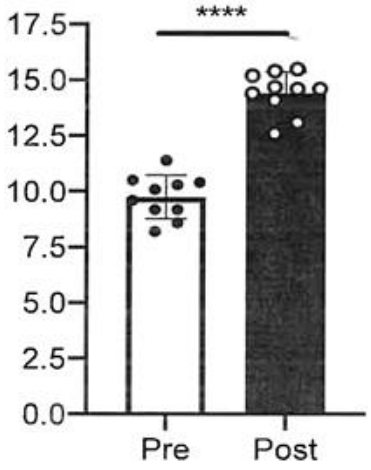
After the treatment of 30 days, 15 patients (75%) had very good improvement of symptoms, 3 patients (15%) had moderate improvement, 2 patients (10%) had mild improvement and there was no dropout from the study.

IMPROVEMENT IN LABORATORY FINDINGS

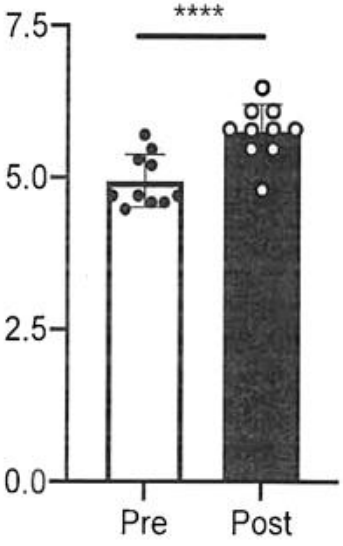
PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



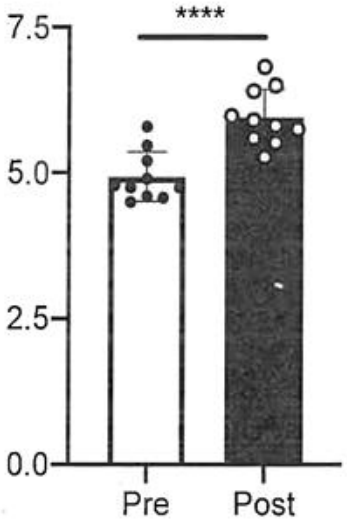
Hemoglobin Cohort A



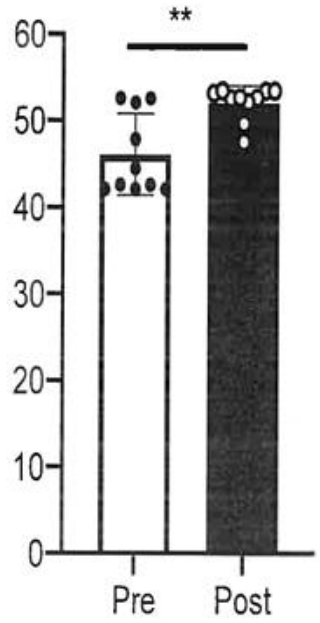
HemoglobinCohort B



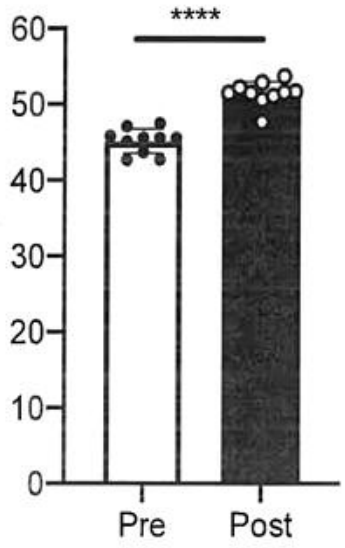
RBC countCohort A



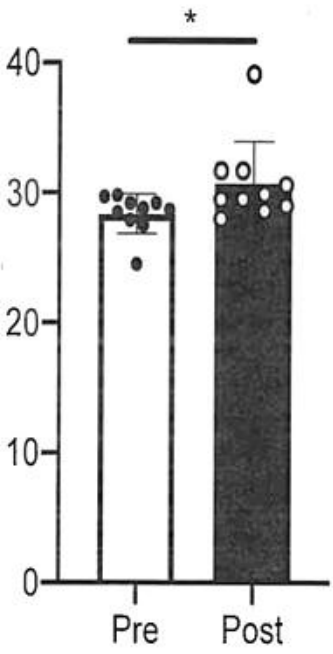
RBC countCohort B



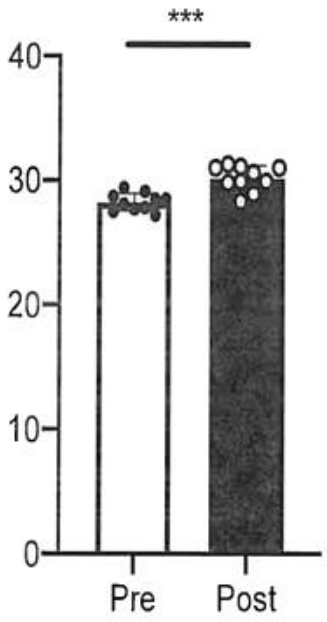
17-hydroxy progesteroneCohort A



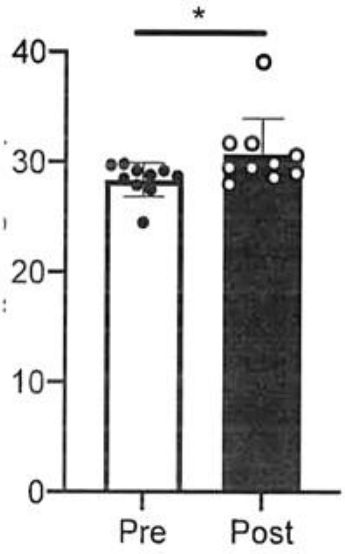
17-hydroxy progesteroneCohort B



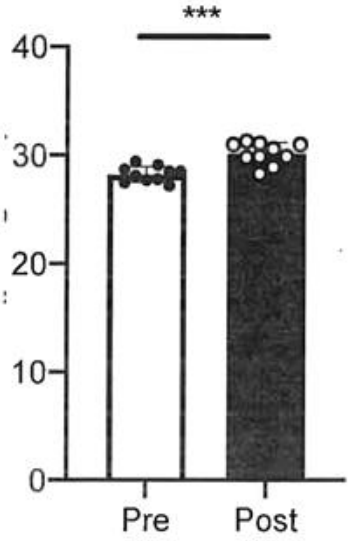
TestosteroneCohort A



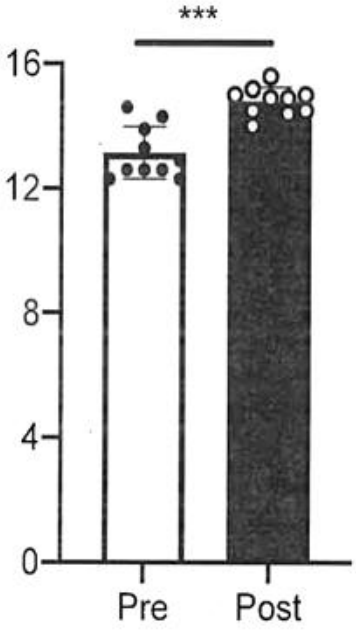
TestosteroneCohort B



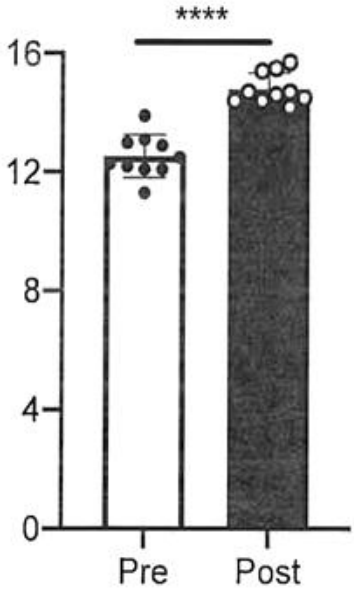
TSHCohort A



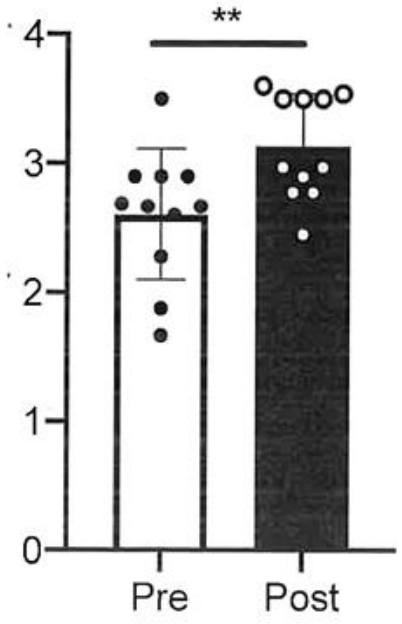
TSHCohort B



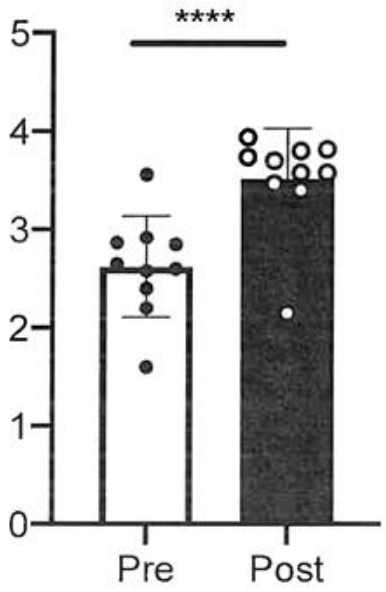
Cortisol Cohort A



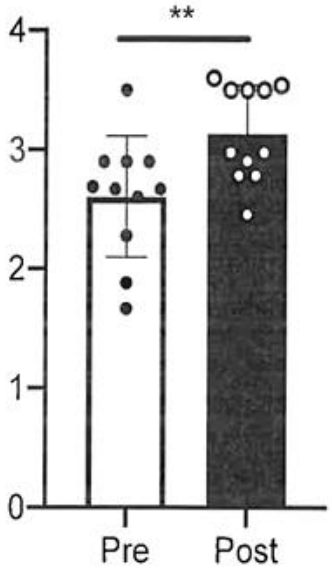
Cortisol Cohort B



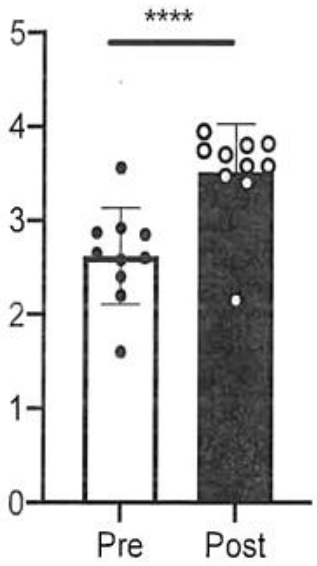
Prolactin Cohort A



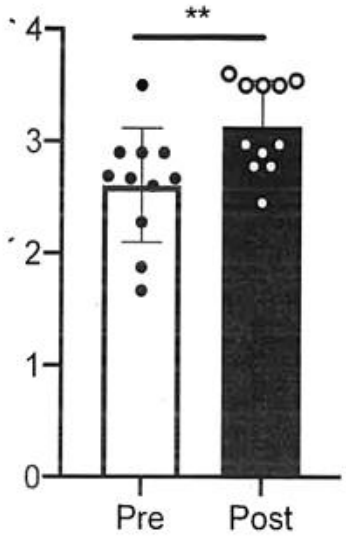
Prolactin Cohort B



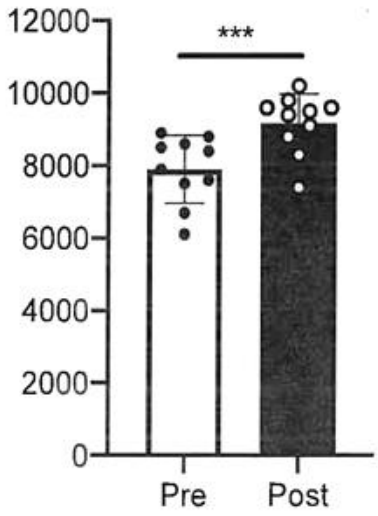
FSH Cohort A



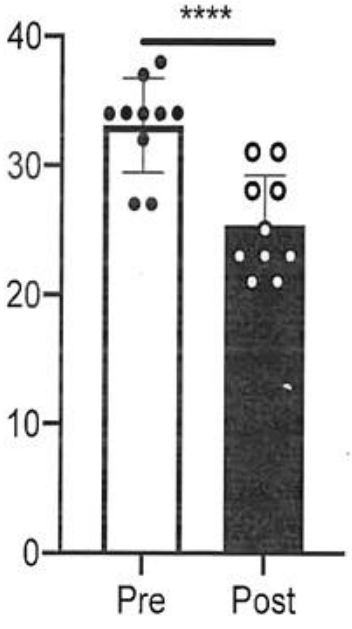
FSH Cohort B



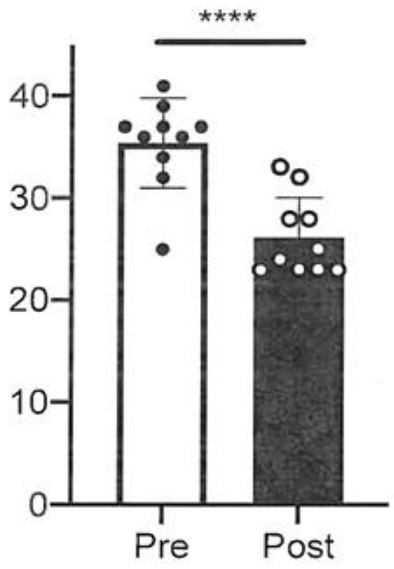
WBC Cohort A



WBC Cohort B



Lymphocytes Cohort A



Lymphocytes Cohort B

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 lable 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 form sareproperly 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 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

The current Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trialsis designed to evaluate the efficacy of Proprietary Ayurvedic Medicine- SHILAJIT Capsule, 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 "Sukrasthambana, Dhathuksheena (Oligospermia), Dourbalya (Nervous weakness) associated with Loss of libido, erectile dysfunction etc,"

By consolidating the results obtained in the clinical investigations and laboratory investigations, it is hereby concluded that the Proprietary Ayurvedic Medicine - SHILAJIT CAPSULE, is highly effective in controlling Clinical symptoms o/ "Sukrasthambana, Dhathuksheena (Oligospermia), Dourbalya (Nervous weakness associated with Fatigue,Stress,Loss of libido, erectile dysfunction etc," in the recruited patients.

REFERENCES

1. McKinlay JB, et al. The worldwide prevalence of erectile dysfunction. Int J Impot Res. 2016.
2. Shamloul R, Ghanem H. Erectile dysfunction. Lancet. 2013.
3. Sharma R, et al. The role of testosterone therapy in male sexual dysfunction. J Clin Endocrinol Metab. 2017.
4. Khera M, et al. Risks associated with long-term use of PDE5 inhibitors. Urology. 2018.
5. Sharma PV. Charaka Samhita: Vajikarana and Sexual Health in Ayurveda. Chaukhambha Publications. 2010.
6. Mishra S, et al. Ayurvedic concepts of male sexual health and rejuvenation. J Ayurveda Integr Med. 2018.
7. Wilson E, et al. Shilajit: A traditional panacea with modern applications. J Ethnopharmacol. 2019.
8. Sharma B, et al. The role of Shilajit in improving testosterone levels. Andrologia. 2020.
9. Tiwari V, et al. Shilajit and reproductive health: A clinical review. J Tradit Complement Med. 2021.
10. Mahajan UB, et al. Shilajit and mitochondrial energy production. Phytother Res. 2019.
11. Agarwal A, et al. The role of antioxidants in sperm health. Reprod Biol Endocrinol. 2018.
12. Baliga MS, et al. Clinical evaluation of Shilajit for sexual function. J Ayurveda Med Res. 2019.
13. Patel N, et al. The stress-reducing properties of Shilajit. Evid Based Complement Alternat Med. 2020.
14. Joshi T, et al. Adaptogenic and anti-fatigue properties of Shilajit. J Herb Med. 2022.
15. Gupta V, et al. Nitric oxide modulation by Shilajit in erectile function. J Urol Res. 2021.
16. Mukherjee PK, et al. Shilajit and aging: A review of its bioactive compounds. J Ethnopharmacol. 2020.
17. Srivastava S, et al. Scientific validation of Ayurvedic aphrodisiacs. J Tradit Complement Med. 2020.
18. Patel R, et al. Clinical trials on Shilajit and male vitality. Pharm Biol. 2022.
19. Kar SS, et al. Standardization of Ayurvedic Rasayana formulations. J Herb Med. 2016.

S. Suman, P. Karthikeyan, S. Moulishankar, et.al (2025). Open Label Single Centric Clinical Exploratory Of Efficacy Study On Shilajit Capsule, An Ayurvedic Proprietary Formulation, ijmaes; 11(1); 2160-2178.