Assessment of Comparative Efficacy of *Shephali dal kwath* (Nyctanthus arbor-tristis), *Gomutra ark* (Distillate of cow urine) with *Erand sneha* (Ricinus communis) and *Erand sneha* (Ricinus communis) only in the Management of *Grudhrasi* (Sciatica): Study Protocol

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ABSTRACT-

Background – *Grudhrasi* the name itself indicates the gait of a patient due to extreme pain, just like a vulture *(Gidhha)*. It is one of the major causes of illness in developing countries like India, with variable prevalence ranging from 2% to 40%. As there is no complete cure for the disease available to date, symptoms and disease moderation are the choice of treatment. The long-term use of anti-inflammatory drugs, analgesics, and steroids has been proven to have many adverse effects. This study aimed to provide a better, easier, and affordable treatment through Ayurveda. **Aim-** Assessment of Comparative Efficacy of Shephali dal kwath (Nyctanthus arbor-tristis), Gomutra ark (Distillate of cow urine) with Erand sneha (Ricinus communis) and Erand sneha (Ricinus communis) only in the Management of Grudhrasi (Sciatica) **Objectives-** To compare the efficacy of above three formulations namely Shephali Dal Kwath (Nyctanthes arbor-tristis) orally, Gomutra Ark (Distillate of cow urine) with Erand Sneha (Ricinus communis) orally and Erand Sneha (Ricinus communis) orally in the management of Grudhrasi (Sciatica). **Methods-** Patients aged–20-50 years with clinical signs and symptoms of *Grudhrasi* and not taking any obvious medication for the same will be included in the study with their written consent. Patients will be divided into three groups and will be treated with *Shephali dal kwath (Nyctanthus arbor-tristis), Gomutra ark (Distillate of cow urine)* with *Erand sneha (Ricinus communis)* or Erand sneha *(Ricinus communis)* individually. **Results-** Collected data will be recorded and analyzed with the statistical software STATA version 10.1 (2012). Statistical analysis will be performed using the Wilcoxon signed-rank test, paired t-test, and ANOVA test. **Conclusion -** Long-term use of analgesics and other medications seems dangerous to health. *Shephali dal kwath, Erand sneha* and *Gomutra ark* have significant effects on *Grudhrasi*. This study was an attempt to choose a better combination according to the condition of the patient and the disease (*Rog and Rogi awastha).*

Keywords – *Erand sneha, Gomutra ark, Grudhrasi,* Sciatica**,** *Shephali dal kwath*

Name of Registry: Clinical Trials Registry - India (CTRI)

Registration Number: CTRI NO: CTRI/2022/10/046170

Registration Date: 4-Oct-2022

URL of trial in the registry database:

https://ctri.nic.in/Clinicaltrials/pdf_generate.php?trialid=73472&EncHid=28711.83340&modid=1&compid=19%27,%2773472det%27

1. INTRODUCTION-

Grudhrasi disease is characterized by low back pain as a cardinal symptom. Low back pain refers to the pain that one feels in the lower back. One may also have back stiffness, decreased movement of the lower back, and difficulty in standing straight. [1] The condition resembles the disease *Grudhrasi* mentioned in Ayurveda under the umbrella of *Vatavyadhi*, and in this piercing type of pain, which restricts the movement of the affected leg, makes the walking pattern-like bird vulture *(Grudhavat*) causing disgraceful conditions.[2] Sciatica is a relatively common condition, with a lifetime incidence ranging from 13% to 40%. The annual incidence of an episode of sciatica ranges from 1% to 5%. [3, 4]Approximately two thirds of patients with lower back pain (LBP) also report leg pain. [5],[6],[7] Lack of job satisfaction, depression, obesity, smoking, alcohol and socioeconomic deprivation have also been found responsible for it. The disease is characterized by the onset of *Ruja* (pain), *Toda* (pricking), and *Stambha* (stiffness) to *Kati-Prishtha* (lower back), *Janu* (knee*), Jangha* (thigh), and *Pada* (feet). In contrast, *Acharya Sushruta* opines that there are two *Kandara* in the affected leg. The two *Kandara* include one extending distally from the *Parshni* to the toes, and the other extending above from the Parshni to the *Vitapa*. These two *Kandara* when afflicted with the *Vata Dosha* limit the extension of the leg. This disease is known as *Grudhrasi*. [8], [9], [10] Patients suffering from *Grudhrasi* have restricted movements due to painful limbs, affecting their daily routine activities. The description narrated in these classics exactly coincides with the description of 'Sciatica' including the important diagnostic test SLR which is described as *'Sakthinkshepanigraha'* by our *Acharyas*. In *Grudhrasi*, drowsiness, feeling of heaviness, and anorexia may occur if *Kapha* is associated with *Vata*.[14],[15] In Ayurveda treatment like *Abhyanga, Swedana* and some herbo-mineral medication forms are mentioned for the treatment of *Grudhrasi*.[16] External Snehan *(Abyangha)* is a form of Ayurvedic therapy that involves massage of the body with warm oil. Peer-reviewed medical researchers have shown that the benefits of massage include pain relief; reduced trait anxiety and depression; and temporarily reduced blood pressure, heart rate, and state of anxiety.[17], [18] It also used for the treatment of various *Vata vyadhis*.

Purpose of the study-

There is no complete cure for the disease in modern science, and symptomatic treatments have limitations and adverse effects. Conventional treatment usually advocates analgesics, physiotherapy, and bed rest for sciatica as per the condition. Patients with significant neurological deficits might be advised to undergo surgery.[19], [20] Long-term use of anti-inflammatory drugs, various analgesic drugs, and steroid injections has been proven to have many systemic adverse effects. To date, no satisfactory treatment has been available for Sciatica [20]. Lumbar traction is a commonly used method to treat patients with low back pain

(LBP), with or without sciatica.[21] This study attempted to provide a simple, easy, affordable, and adverse effect of free treatment for the same.

1.1 Aim

To evaluate and compare the efficacy of *Shephali Dal Kwath* (Nyctanthes arbor-tristis), *Gomutra Ark* (distillate of cow urine) with *Erand Sneha* (Ricinus communis), and *Erand Sneha* (Ricinus communis) in the Management of *Grudhrasi* (Sciatica).

1.2 Objectives

I. To assess the efficacy of *Shephali Dal Kwath* (Nyctanthes arbor-tristis) on subjective and objective parameters of *Grudhrasi* (Sciatica).

II. To assess the efficacy of *Gomutra Ark* (distillate of cow urine) with *Erand Sneha* (Ricinus communis) on subjective and objective parameters of *Grudhrasi* (Sciatica).

III. To assess the efficacy of oral administration of *Erand Sneha* (Ricinus communis) on the subjective and objective parameters of *Grudhrasi* (Sciatica).

IV. To compare the efficacy of above three formulations namely *Shephali Dal Kwath* (Nyctanthes arbor-tristis) orally, *Gomutra Ark* (Distillate of cow urine) with Erand Sneha (Ricinus communis) orally and *Erand Sneha* (Ricinus communis) orally in the management of *Grudhrasi* (Sciatica)

METHODS

Selection of the study subjects-

1.1.1 Inclusion Criteria:

Patients aged–20-50 years with clinical signs and symptoms of Grudhrasi and not taking any obvious medicine for the same will be included in the study with their written consent.[22]

2.1.2 Exclusion Criteria:

Patients with systemic diseases such as Uncontrolled DM, Heart disease, renal disease, Cancer, Tuberculosis, and other major health problems were excluded from the study. Pregnant and Lactating women, and patients suffering from some disease conditions such as fibrositis of sacral ligaments, tumors of the cauda equina, Pitta prakruti, and severe gastritis will be excluded from the study.[22]

2.1.3 Diagnostic criteria [23]:

Criteria for diagnosis will be based on signs and symptoms available in Ayurvedic and Modern texts, as well as with the help of the following parameters.

1. Presence of pain, stiffness, pricking pain, numbness, anorexia, and drowsiness.

2. Tenderness along the course of sciatic nerve.

3. S.L.R. test in affected leg as objective measure for diagnosis as well as for improvement of the treatment.

4. Walking time

5. Schober's test

6. Bowstring test

2.1.4 Assessment Criteria-

A. Objective criteria-

1. The Straight Leg Raising (SLR) test is also described in Ayurveda as Sakthikshepannigraha.[24] SLRT positive for more than 900 will be graded as 0, from 710 to 900 will be graded as 1, and so on gradually up to 310 and less than 300 will be graded as 4.

2. Walking time – time taken to cover 21 m by the patient will be graded from grade 0 (20 s) to grade 4 (51-60 sec).

3. Schober's Test- Normal > 5cm, abnormal < 2.5 cm

4. Bowstring test [25] -Tension on the sciatic nerve after performing the test in supine position will be consider as positive.

B. Subjective Criteria-

Ruja (severity of pain) by VAS scale, *Stambha* (stiffness), *Toda* (pricking pain), *Muhuspandana* (numbness), *Aruchi* (anorexia), Tandra (drowsiness), and magnitude of pain, all of which will be assessed and graded from 0 to 4.

Functional disability was assessed using the Oswestry Disability Assessment Questionnaire. [26] Disability level was scored from 0 to 50 as no disability to complete disability.

1.2 Study design, sampling procedure and Sample selection techniques:

Randomized, Reference Standard, Controlled, Single-blind (assessor), and superiority clinical trial. Randomization using the computer-generated table method was used for sampling. This study was conducted in two phases.

1. Pilot study - To decide the exact dose of the trial drug.
2. Study group.

1.3 Sample Size Calculation:

Considering effectiveness by calculating the mean difference of the main objective criteria SLR (20% difference) reported in an article–clinical study to evaluate the efficacy of Shephali (Parijatak) Patra Kwath (decoction of Nyctanthus arbor-tristis leaves) in the management of Ghridhrasi by Vd. Anupam Shok Alman, MD Kayachikitsa with the following assumption: [27]

The formula for sample size calculation-

Mean difference =1.14

Standard deviation = 0.349

Clinically, the relevant difference (d) = (Assumed 20% decrease) = 0.228, as per

Reference article values (Before & after for SLR)

Taking 20% difference as effect size.

$N = \{Z_{1-} \alpha/_2 \sqrt{2}\, P(1 - P) + Z_{1-\beta} \sqrt{P_1 (1 - P_1) + P_2 (1 - P_2)}\}2/ (P1 - P2)2$

N= 41 each group by considering 10% Drop out.

1.4 Plan of Study

A. On the basis of this published standardization available on API-*Ayurvedic* Pharmacopeia of India, as a single drug, the standardization of these drugs will be performed. Macroscopic, microscopic, physicochemical, and microbiological tests will be performed at the Pharmaceutical Laboratory of Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod, Wardha.

B. Preparation of Drug:

1. *Shephali Dal Kwath* - *Kwath* will be prepared according to *Kwath kalpana* (decoction procedure), as explained in *Bhaishajya Ratnavali.* [28] And will be administered 40 ml BD after a meal.

2. *Gomutra Ark* (distillate of cow urine) of 25 ml quantity was mixed with 6 ml of *Erand Sneha* (Ricinus communis) at the time of dosing (at sleep time 30 min after meal), as mentioned in *Bhaishajya Ratnavali.* [29]

3. 6 ml of *Erand Sneha* with lukewarm water will be given to patient at bed time.

C. According to the inclusion criteria, patients will be assessed and included in the study after obtaining written consent. Randomization of patients will be performed using the computer-generated table method, and the patients will be divided into three groups. After administration of the drugs, follow-up will be performed on the 7th, 14th, 21st and 28th days of treatment. The collected data will be arranged in a master table and statistically analysed.

Participant timeline- Patients will be treated for 28 days and assessment will be done up to 6 months as mentioned in Figure 1**.**

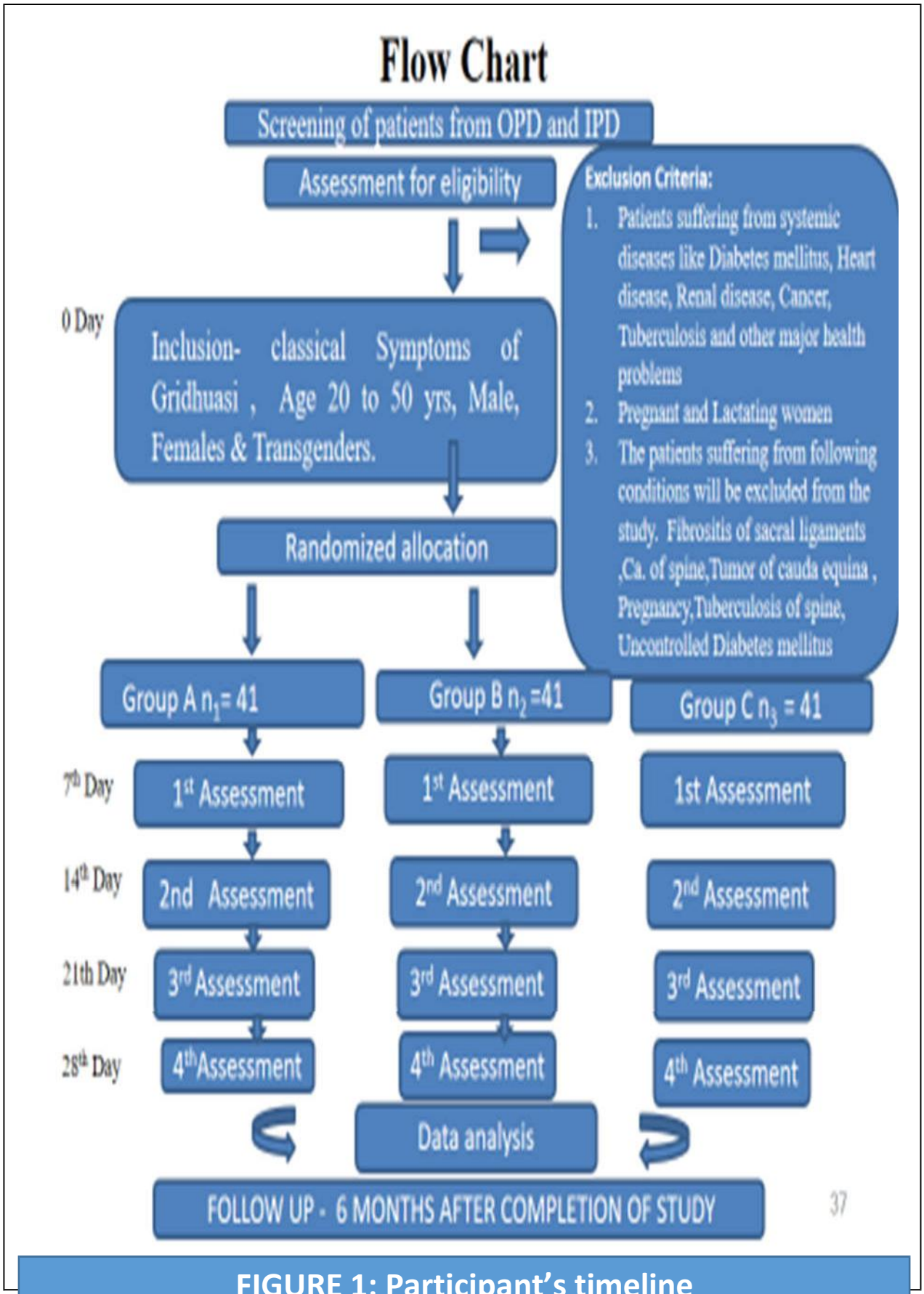

FIGURE 1: Participant's timeline

1.5 Statistical analysis

The data were entered into a Microsoft Excel spreadsheet. Categorical variables will be compared before and after treatment in each group using Wilcoxon sign rank test. % effect of the three groups will be compared by ANOVA test. Objective parameters will be compared before and after treatment in each group using paired t test. % effect of the three groups will be compared by performing an independent ANOVA test. Statistical significance was set at $P< 0.005$.

3. OBSERVATIONS AND RESULTS

Stepwise observations will be recorded and presented in the form of tables, charts, and pictures. The results will be drawn appropriately on the basis of statistical analysis, and conclusions will be drawn in relation to the study objectives.

4. DISCUSSION

A higher incidence of *Grudhrasi* (sciatica) indicates the need for a permanent solution. A study by Dr. Mali showed that the incidence of *Grudharsi* was 97.5% in the urban population. Anti-inflammatory drugs, such as NSAIDS, are most commonly used in the treatment of sciatica. Thus, the enormous expense associated with NSAID success is apparent. Thirty percent of hospital admissions for avoidable adverse medication reactions are associated with NSAIDS. [30]

Ayurveda suggested drugs with fewer adverse reactions and toxicity. Using this herbo-mineral drug, we can decrease the morbidity of the disease. In Ayurveda texts, we obtain references from *Shefali Patra, Gomutra Arka* and *Erand Sneha* in the management of *Gridhrasi*. Some clinical studies have also shown better efficacy of *Shefali Patra* in *Grishrasi*. Some preparations of *Gomutra Arka* have also shown great efficacy in the *Gridhrasi*. Therefore, we aimed to compare the efficacy of all drugs and their combined effects. Thus, it helps to choose the correct combination and reduce the treatment time by providing more efficacy in a specific cohort of symptoms.

5. CONCLUSION

The present study aimed to compare the efficacy of *Shephali Dal Kwath, Gomutra Ark, Erand Sneha* and *Erand Sneha* in the management of *Grudhrasi* (Sciatica). This is a genuine attempt based on the available literature. Observation, results, discussion, and conclusions are drawn, and the entire thesis work is summarized.

6. SCOPE OF STUDY

This study may contribute to providing effective therapy for Grudhrasi or Sciatica, with an *Ayurvedic* treatment regimen that is non-invasive and easy to perform. The effectiveness of the individual drugs according to type and *Awastha* of the *Grudhrasi* can be understood, which may help to decide the drug of choice in a specific state of *Grudhrasi.*

7. CONSENT

The aim and details of the study will be explained to the patients thoroughly in their vernacular language, and written consent will be obtained with the intention to treat them.

8. ETHICAL APPROVAL

The approval will be taken from the institutional ethical committee.

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9. CONFLICT OF INTERESTS

The authors and coauthors have voluntarily declared that there are no conflicts of interest.

10. GRANT INFORMATION

This article does not include any sponsorship or financial support from a third party.

11. DISSEMINATION

This protocol will be further published as a thesis to disseminate the study for *Grudhrasi* (sciatica). The study protocol provides a detailed overview of the study design, methodology, data collection procedures, data analysis plan, and ethical considerations. By disseminating this protocol, we hope to advance knowledge in the field and facilitate future research.

Note

The study demonstrates the effectiveness of “Ayurveda,” an old practice practised in several regions of India. If it is determined that this ancient idea is appropriate, it should be thoroughly assessed and partially implemented.

12. DATA AVAILABILITY

Underlying data

No data are associated with this article.

Reporting guidelines: https://doi.org/10.5281/zenodo.11392999

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