

# Evaluation of Comparative Efficacy of *Goghrita* with *Saindhava Matrabasti* versus *Goghrita Matrabasti* in Sciatica (*Gridhrasi*): A Randomised Controlled Trial Research Protocol

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## ABSTRACT

**Introduction:** Modern lifestyles contribute to nutritional deficiencies and health issues, with low back pain affecting 80-90% of individuals. Sedentary living, poor posture and stress often lead to sciatica, characterised by pain radiating down the leg, which is classified in Ayurveda as *Gridhrasi*, a *Vata* disorder.

**Need for the study:** Due to sedentary lifestyles, poor posture and job challenges, sciatica is becoming increasingly common. Traditional therapies have significant disadvantages. While contemporary treatments such as analgesics, physiotherapy, or surgery frequently alleviate symptoms, they do not address the underlying issues. Recurrence and adverse effects are common. Ayurvedic therapies that provide comprehensive and long-lasting relief, such as *Matrabasti*, require evidence-based acceptance. This treatment reduces pain and stiffness by lubricating the muscles and nerves.

**Aim:** To evaluate and compare the efficacy of *Goghrita* (cow clarified butter) with *Saindhav Lavana* (rock salt) *Matrabasti* (enema) versus *Goghrita Matrabasti* in *Gridhrasi* (sciatica).

**Materials and Methods:** A randomised single-blind (assessor) superiority trial will be conducted at the Department of Panchakarma, Mahatma Gandhi Ayurved College Hospital and Research Centre (MGACHRC), Salod Hirapur (H), Maharashtra, India, from November 2024 to January 2026. Subjects will be divided into two groups of 30 each. In group A (Control), *Goghrita Matrabasti* 60 mL will be administered after meals for nine days and in group B (Experimental), *Goghrita* 60 mL with 5 grams of *Saindhav Lavana* will be given after meals for nine days. The assessment will be based on subjective parameters such as *Spandana* (Twitching), *Ruk* (Pain), *Stambha* (Stiffness), *Toda* (Pricking pain), *Aruchi* (Loss of taste), *Tandra* (Stupor) and *Gaurava* (Heaviness), as well as objective criteria including the Visual Analogue Scale (VAS) scale, the Straight Leg Raising Test (SLRT), Range of Motion and the Schober test on the 0<sup>th</sup>, 9<sup>th</sup>, 18<sup>th</sup> day. Statistical analysis will be conducted using paired and unpaired t-tests for intra- and intergroup comparisons and a Chi-square test for categorical data. A p-value <0.05 will be considered statistically significant.

**Keywords:** Cow clarified butter, Range of motion, Rock salt, *Sneha basti*, Straight leg rising test

## INTRODUCTION

Modern lifestyles often lead people away from a nutritious diet, resulting in various health issues. Low back pain affects 84% of individuals at some point [1]. Sedentary living, stress, poor posture, jerky movements, extensive travel and other factors exert pressure on the spine and lower pelvis. The most typical symptom of sciatica is pain radiating down the back of the leg [2]. Sciatica (*Gridhrasi*) is associated with factors such as spinal trauma (*Abhighata*), posture problems (*Vishamachesta*), overloading (*Bharavahana*), sudden imbalanced movements (*Atichesta*), sedentary living and psychological stress (*Chinta*, *Shoka*). In Ayurveda, it is classified as *Gridhrasi*, a *Vata* disorder among the 80 *Vata Nanatmaja Vyadhi* [3]. *Gridhrasi*, or sciatica, manifests as low back pain radiating to the buttocks and down the leg, often causing tingling and numbness. Prolonged sitting may exacerbate the pain, as it compresses the nerve by 30% [4]. Management of *Vata* starts with *Snehan* and *Swedan*, followed by oral medicines and *Basti Karma* [5]. *Basti Karma* balances the three *Doshas* and is referred to as "Half of the treatment" by *Charaka* [6]. *Matra Basti* is a safe and versatile treatment suitable for any age group, with no strict regimen and does not require *Purva*, *Paschat*, or *Samsarjana Krama*. Compared to other medications, *Goghrita* offers a convenient and approachable alternative due to its easy accessibility [7].

*Goghrita* acts as *Rasayana*, *Vrishya*, *Agnivardhaka*, *Rasavardhaka*, *Balya*, *Ojovardhaka*, *Kantivardhaka*, *Indriyabalavridhdikar*, *Buddhivardhaka*, *Vayahasthapana*, *Unmadahara* and more. It pacifies *Vata* through *snigdha*guna, *Pitta* through *madhura* rasa and *Shaityata* and *Kapha* by processing with *Kaphahara* drugs [8]. *Saindhav Lavana* increases the efficacy of *Matra Basti*, alleviates *Vibandha* (constipation) and *Stambha* (stiffness) and enhances *Agni* [9]. *Basti* is a Panchakarma enema procedure. While formulating the *Basti* liquid, rock salt is added to create an emulsion. This process helps to dissolve and expel *Doshas* from the intestines [10].

## REVIEW OF LITERATURE

According to *Acharya Harita*, *Gridhrasi* is classified as a *Vyanaprakopaja* disease. It occurs due to the vitiation of *Vyana Vayu*, which governs all forms of voluntary movements, including expansion, contraction and movements in upward, downward and oblique directions [11].

No other treatment can pacify and regulate *Vata* as effectively as *Basti*. The concept of preparing *Sneha* for optimal absorption is enhanced by the addition of *Lavana*, which improves the bioavailability of *Sneha* when administered together. Consequently, many *Vatanashaka Sneha* yogas described by the *Acharyas* include *Lavanas* as one of their components [12].

*Goghrita*, a type of clarified butter, is known to improve *Ojas* (vitality), memory, intelligence and digestion. It also alleviates conditions such as fever, consumption, insanity and poisoning, as well as *Vata* and *Pitta* imbalances. Among all the unctuous substances, *Goghrita* is considered the best. It is auspicious, cool in potency and sweet in taste. Its benefits multiply a thousandfold when taken as directed, helping to manage *Pitta* imbalances and assist in treating mental illnesses. *Acharya Charaka* has classified *Goghrita* as *Vata Shamaka* (which pacifies *Vata Dosha*) and categorised it as *Madhura Rasa* (sweet taste). Additionally, *Goghrita* possesses antioxidant and anti-inflammatory properties [13,14].

A comparative study by Gaonkar SG and Basarigidad JP investigated the efficacy of *Sahachara Taila Matrabasti* and *Ashtakatwara Taila Matrabasti* in treating *Gridhrasi*. Both treatments significantly improved pain (*Ruk*), stiffness (*Sthambha*) and functional parameters such as lumbar flexion and walking time, with *Ashtakatwara Taila* demonstrating slightly better outcomes in reducing symptoms and enhancing functionality [15].

Further evidence on the effectiveness of *Saindhava Lavana* in Ayurvedic therapies for *Vatavyadhi* has been documented by Shenoy SU et al., [12]. They found it beneficial for managing disorders related to *Vata Dosha* and stated that *Sneha* and *Saindhava Lavana* support neural function, balance *Vata* and aid in the management of *Vatavyadhi* by ensuring proper nerve conduction and integrity [12].

To the best of our knowledge, no study has been conducted on the efficacy of *Goghrita Matra Basti* and *Saindhava* in treating Sciatica. Therefore, the present study aims to compare the efficacy of *Goghrita* with *Saindhava Matrabasti* against *Goghrita Matrabasti* in treating Sciatica (*Gridhrasi*).

#### Primary objectives:

- To evaluate the effect of *Goghrita* with *Saindhav Lavana Matra Basti* in sciatica (*Gridhrasi*).
- To evaluate the effect of *Goghrita Matra Basti* in sciatica (*Gridhrasi*).

**Secondary objectives:** To compare the effects of *Goghrita* with *Saindhav Lavana Matra Basti* and *Goghrita Matrabasti* in sciatica (*Gridhrasi*).

**Null hypothesis (H0):** There will be no significant difference between the efficacy of *Goghrita* with *Saindhav Lavana Matra Basti* and *Goghrita Basti* in the management of Sciatica (*Gridhrasi*).

**Alternative hypothesis (H1):** *Goghrita* with *Saindhav Lavana Matra Basti* will be more efficacious than *Goghrita Basti* in managing Sciatica (*Gridhrasi*).

## MATERIALS AND METHODS

A randomised single-blind (assessor) superiority trial will be conducted at the Department of Panchakarma, MGACHRC, Salod, Maharashtra, India, from November 2024 to January 2026. The Institutional Ethical Committee (IEC) of DMIHER, Wardha, Maharashtra, has granted permission for the study, with reference number MGACHRC/IEC/Sep-2023/755. The trial is registered on the Clinical Trial Registry - India (CTRI) portal with reference number CTRI/2024/05/068185. An informed consent form outlining all the specifics of the study will be provided to participants in their native language before the trial commences. Participants' personal information will be collected and kept confidential before, during and after the study. The committee will supervise the trial's progression. The researcher will monitor any adverse events and notify the ethical committee. Only the researcher will have access to the data, which will be stored in a secure location. Participant allocation will be carried out using opaque, sealed envelopes with sequential numbers for group A or B by a second person, in accordance with the Sequentially Numbered, Opaque, Sealed Envelope (SNOSE) scheme, to avoid bias in the study.

#### Inclusion criteria:

- Patients willing to provide written informed consent.
- Patients aged 20 to 60 years of either sex.
- Patients diagnosed with *Gridhrasi* based on subjective and objective assessments [16].
- Subjects showing a positive SLRT with 30 to 70° of hip flexion [17].
- Patients deemed fit for *Basti Karma* as per *Ayurvedic* classics.

#### Exclusion criteria:

- Patients with a history of traumatic injury.
- Patients with a history of bone tumours, cancer of the spine, tuberculosis of the vertebral column, fibrosis of the sacral ligaments and protruded intervertebral discs.
- Patients suffering from diabetes mellitus, heart disease, renal disease, cancer, tuberculosis, or other significant health issues.
- Pregnant or lactating women.

**Sample size calculation:** Formula applied is Cohen's effect size formula. An effect size of 0.8 is considered large.

$$\text{Effect size } d = \frac{\mu_2 - \mu_1}{\sigma} = 0.8 \text{ (Estimated)}$$

$$\text{Sample size } N = \left( \frac{1+r}{r} \right) \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2}{d^2} + \frac{Z_{1-\alpha/2}^2}{2(1+r)}$$

Considering a large effect size difference = 0.8 (large effect size).

$Z_{1-\alpha/2}$  at a 5% level of significance = 1.96

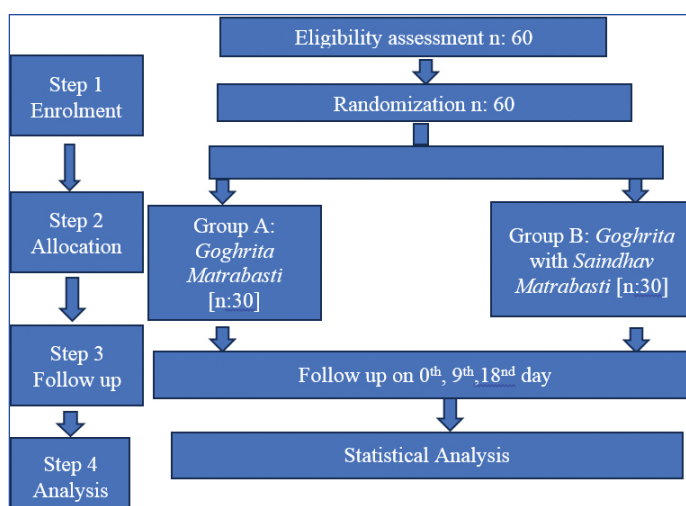
$Z_{1-\beta}$  at 80% power = 0.84

Ratio allocation (group 2/group 1) = 1.

$$\text{Sample size } n = \left( \frac{1+1}{1} \right) \frac{(1.96 + 0.84)^2}{0.8^2} + \frac{(1.96)^2}{2(1+1)} = 26 \text{ per group.}$$

Considering a 15% dropout rate, a total of 4 participants should be added. Therefore, a total of 30 samples are required per group.

Thus, 60 patients will be included and divided into two groups: group A (N=30), receiving *Goghrita Matrabasti* (control group) for nine days and group B (N=30), receiving *Goghrita Matrabasti* with *Saindhav* (experimental group) for nine days [Table/Fig-1,2].



[Table/Fig-1]: Consolidation Standards of Reporting Trials (CONSORT) flow chart.

Group	Sample size	Intervention	Dose and frequency	Duration	Follow-up
A	30	<i>Goghrita Matrabasti</i>	60 mL after meal once a day	9 days	0 <sup>th</sup> , 9 <sup>th</sup> , 18 <sup>th</sup> day
B	30	<i>Goghrita</i> with <i>Saindhav Matrabasti</i>	60 mL with 5 gm <i>saindhav</i> after meal once a day	9 days	

[Table/Fig-2]: Grouping and posology.

### Preprocedure (*Poorva Karma*) for Medicated Oil Enema

The preparation for the medicated oil enema (*Basti*) will involve the use of *Goghrita* and *Saindhav Lavana*, which will be purchased from Dattatray Pharmacy located at the hospital to ensure they meet quality standards.

**Preparation of the patient:** Patients will be advised to have adequate fluid intake after consuming a light meal, which should be one-fourth of their usual intake. Following the meal, patients will be encouraged to take a short walk to facilitate the evacuation of both stool and urine.

### Main Procedure (*Pradhana Karma*)

The patient will be positioned on the massage table (*Droni*) in the left lateral position (*Vama Parshwa*), with their right leg flexed. The anal area and the catheter tip will be lubricated before gently inserting one-fourth of the rubber catheter into the anal canal.

The lukewarm medicated enema will then be administered using a syringe, as follows:

Group A: 60 mL of *Goghrita*.

Group B: 60 mL of *Goghrita* with 5 g of *Saindhav Lavana*.

The procedure will be repeated for nine days. After the procedure, the catheter will be removed slowly to prevent complications.

### Follow-up Procedures (*Paschat Karma*)

The subjects will then rest in a supine position and count to 100, which will allow the medicated enema to spread throughout the body. The back and buttocks will be rubbed with both palms and participants will be instructed to remain as composed and still as possible, avoiding yelling or causing unnecessary disturbances [18].

### Outcomes:

Subjective parameters will be assessed on the 0<sup>th</sup>, 9<sup>th</sup> and 18<sup>th</sup> days, Subjective criteria is shown in [Table/Fig-3].

1. <i>Stambha</i> (Stiffness)	Grade
No stiffness	0
Occurs sometimes for 5-10 minutes	1
Occurs daily for 10-30 minutes	2
Occurs daily for 30-60 minutes	3
Occurs daily for more than 1 hour	4
2. <i>Ruk</i> (Pain)	
No pain	0
Occasional pain	1
Mild pain with walking difficulty	2
Moderate pain with slight difficulty in walking	3
Severe pain with significant difficulty in walking	4
3. <i>Toda</i> (Pricking sensation)	
No pricking sensation	0
Occasional pricking sensation	1
Mild pricking sensation	2
Severe pricking sensation	3
4. <i>Spandana</i> (Twitching)	
No twitching	0
Occurs sometimes for 5-10 minutes	1
Occurs daily for 10-30 minutes	2
Occurs daily for 30-60 minutes	3
Occurs daily for more than 1 hour	
6. <i>Aruchi</i> (Loss of taste)	
No anorexia	0
Mild anorexia	1

Moderate anorexia	2
Severe anorexia	3
7. <i>Tandra</i> (Stupor)	
No stupor	0
Mild stupor	1
Moderate stupor	2
Severe stupor	3
8. <i>Gaurava</i> (Heaviness)	
No heaviness	0
Mild heaviness	1
Moderate heaviness	2
Severe heaviness	3

[Table/Fig-3]: Subjective parameter and grading.

### Objective criteria:

**Visual Analog Scale (VAS) [20]:** The VAS severity rating will be represented by a 100-millimetre line, with the endpoints marked as “no pain” and “most severe pain.” Participants will be instructed to mark the line corresponding to their current level of pain. The difference between the pretreatment and post-treatment pain scores will be measured and their VAS difference score will be noted.

**Straight Leg Raise Test (SLRT) [17]:** In this test, the patient will lie in a supine position, with their head slightly extended and their hips and legs kept in a neutral position. Hip abduction or adduction will be prohibited, as will internal or external leg rotation. The affected leg will then be slowly and gradually elevated by the ankle, with the knee fully extended. When pain occurs, the examiner will stop elevating the leg further and record the range of motion and the distribution of discomfort.

### Range of Motion [21]

**Active range of motion:** Patients will be asked to perform movements independently, allowing clinicians to observe their willingness to move, coordination and pain levels.

**Passive Range of Motion (PROM):** The clinician will move the patient's joints without their assistance to assess the maximum range of motion.

**Schober test:** The patients will stand upright and the examiner will mark the L5 spinous process with a horizontal line. A second line will be drawn 10 cm above the first. The patient will be then asked to bend forward as if trying to touch their toes and the examiner will measure the distance between the two lines in the flexed position using a measuring tape [22].

## STATISTICAL ANALYSIS

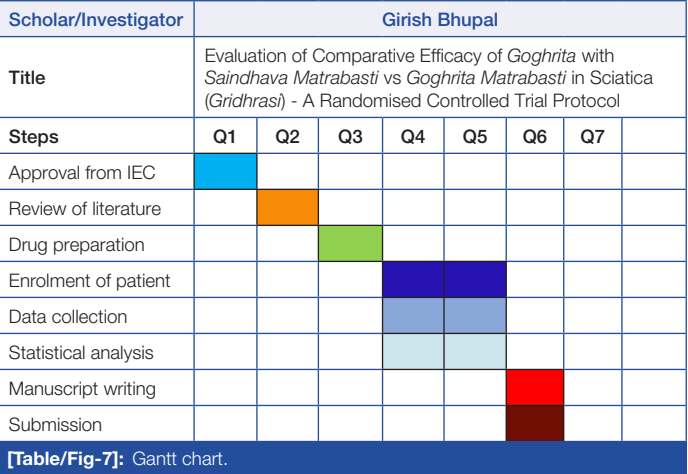
Statistical Package for the Social Sciences (SPSS) version 22.0 will be used for statistical analysis. The paired and unpaired t-tests will be applied for intragroup and intergroup comparisons, while a Chi-square test will be used for categorical data. A p-value <0.05 will be considered statistically significant.

**Intervention modification:** Any adverse side-effects will be recorded and reported to the ethical committee during the treatment. Appropriate treatment will be provided to subjects for any adverse outcomes. Those who choose to withdraw at any point during the study will be allowed to do so, with the reasons for their withdrawal recorded.

**Guidelines:** This protocol will adhere to the Standard Protocol Items: Recommendations For Interventional Trials (SPIRIT) guidelines.

**Data monitoring:** Data monitoring will be supervised by a formal committee. Gantt chart of the present study has been presented in [Table/Fig-7].





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**Authors’ contribution:** GB: Collected the data, SP: Contributed to supervision and conceptualisation, MN: Performed validation and formal analysis and SP: Responsible for review and editing.

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- For any images presented appropriate consent has been obtained from the subjects. NA

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