

Comparative Study on Efficacy of *Marma Chikitsa* and *Agnikarma* in Pain Management of Knee Joint: Protocol for a Randomised Controlled Trial

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ABSTRACT

Introduction: Knee pain, often linked to Osteoarthritis (OA), presents substantial challenges in pain management and functional improvement. Traditional Ayurvedic therapies, such as *Agnikarma* (therapeutic heat application) and *Marma Chikitsa* (stimulation of vital energy points), have long been used for pain relief. The study draws on the anatomical descriptions in Acharya Sushruta's *Sharirsthana*, particularly '*Marma Vigyana*,' which highlights the importance of 107 Marma points.

Need of the study: *Agnikarma* and *Marma Chikitsa* are two different techniques used for treating knee joint pain. *Agnikarma* has several contraindications, including use in *Pitta Prakruti*, children, the elderly, patients with multiple wounds, and during summer. Improperly performed *Agnikarma* can cause complications and requires costly, specialised instruments. In contrast, *Marma Chikitsa* is cost-effective, requires no instruments, has minimal complications, and can be self-administered after training. Although both methods show promise, comparative studies with modern physiotherapy are

limited. The present study aims to address this gap and provide evidence for integrating traditional and modern approaches to knee pain management.

Aim: The current study aims to evaluate the efficacy of *Marma Chikitsa* and *Agnikarma* in pain management of the knee joint.

Materials and Methods: A randomised controlled open-label equivalence clinical trial will be conducted at Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India from October 2024 to October 2026. A total of 78 patients diagnosed with knee joint pain will be recruited and randomly allocated into two groups: Group A (*Marma Chikitsa*) and Group B (*Agnikarma*). Pain intensity {Visual Analogue Scale (VAS)}, functional status (Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Index), Range of Motion (ROM) (Goniometer), and walking time before and after interventions will be assessed on zero-day, seventh day and 15th and final analysis at 30th Day. Statistical data will be expressed as mean±SD, and paired t-test and unpaired t-test will be applied. A p-value <0.05 will be considered statistically significant.

Keywords: Ayurvedic Therapy, *Janusandhigat vata*, Integrative pain management

INTRODUCTION

Knee OA is the most prevalent chronic degenerative disorder of the musculoskeletal system and a leading cause of pain, disability, and impaired mobility worldwide. According to the Global Burden of Disease (GBD) 2021 study, approximately 595 million people worldwide were affected by OA, with the knee joint being the most commonly affected site [1]. A large population based meta-analysis further reported that the global prevalence of knee OA is 16.0% in individuals aged ≥15 years and rises to 22.9% in those aged ≥40 years, indicating a rapidly increasing disease burden with ageing populations [2].

Knee OA significantly compromises functional mobility, activities of daily living, and overall quality of life. Chronic pain, joint stiffness and reduced walking capacity are common consequences. In addition, knee OA is associated with substantial healthcare expenditure, long-term use of medications, frequent physiotherapy, loss of work productivity, and increased surgical burden, thereby imposing a major socioeconomic impact on individuals and healthcare systems [3].

Conventional management of knee OA primarily includes analgesics, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), physiotherapy and joint replacement surgery in advanced cases. While these approaches offer symptomatic relief, they do not modify disease progression, and long-term NSAID use is associated with gastrointestinal, renal, and cardiovascular adverse effects. Moreover, many patients experience incomplete pain relief, recurrence of

symptoms, and functional limitations, highlighting the need for safest and cost-effective procedure that address both pain and functional disability [4].

In this context, Ayurveda describes several non-pharmacological therapeutic interventions for musculoskeletal disorders, among which *Agnikarma* and *Marma Chikitsa* are of special clinical significance. *Agnikarma* is described as a para-surgical procedure involving controlled therapeutic cauterisation using heated metallic instruments, indicated in disorders of *Vata-Kapha* dominance, including *Sandhigata Vata* (OA), *Gridhrasi* (sciatica), *Snayugata* disorders, and chronic pain conditions. Classical clinical studies have demonstrated that *Agnikarma* provides rapid pain relief, reduces stiffness, and improves outcomes in knee OA, with minimal adverse effects when performed properly [5].

Marma Chikitsa is based on the therapeutic stimulation of *Marma* points, which are described as vital anatomical locations formed by the confluence of muscle, blood vessels, ligaments, bones, and joints. Acharya Sushruta has described 107 *Marma* points in the human body and emphasised their critical therapeutic importance [6]. The term *Marma* is derived from the Sanskrit root "*Mru*", indicating vulnerability and vital life-supporting structures [7]. *Marma Chikitsa* has traditionally been used in musculoskeletal pain, joint disorders. Therapeutic stimulation of these points is believed to regulate *Prana* (vital energy), neuromuscular coordination, circulation, and tissue metabolism, resulting in relief in pain, inflammation, stiffness, and movement restriction [8].

Although traditional *Vaidyas* widely practice both therapies, their systematic integration into routine clinical practice remains restricted due to a lack of comparative clinical evidence. Therefore, the present study has been undertaken to compare the efficacy of *Marma Chikitsa* and *Agnikarma* in managing knee joint pain (*Janusandhigata Vata*). If proven effective, the current study will contribute objective clinical evidence supporting the integrative application of these therapies in contemporary musculoskeletal care. This approach addresses a significant gap in the existing scientific literature.

REVIEW OF LITERATURE

Agnikarma, an important therapeutic modality in Ayurveda, is widely employed for the management of *Sandhigata Vata* (OA of the Knee Joint) [5]. Several clinical studies have evaluated its efficacy using various types of *Shalaka* (metal rods), demonstrating both clinical relevance and therapeutic potential in reducing pain and inflammation.

Jethava NG et al., evaluated the role of *Agnikarma* in *Sandhigata Vata* using Rajata (silver) and Loha (iron) *Shalakas*. No statistically significant difference was observed between the two groups; Loha *Shalaka* showed better subjective pain relief. Therefore, he concluded that *Agnikarma* is a simple, non-pharmacological Outpatient Department (OPD) procedure that can be effectively utilised for pain management in *Sandhigata Vata*. However, limitations such as small sample size, absence of a control group, and short follow-up duration were noted, which may affect the generalisability of the results [5].

In another clinical trial, Chavan-Matekar M studied the therapeutic effect of *Agnikarma* using *Tamra Shalaka* (copper rod) in *Janusandhigata Vata*. The results demonstrated a statistically significant improvement ($P < 0.0001$) in key symptoms such as *Shoola* (pain) and *Shotha* (swelling), suggesting the potential of *Tamra Shalaka* as an effective tool in the management of OA [9].

Pandey R and Dhudhmal TS further investigated the combined effect of *Agnikarma* and *Panchatikta Guggulu*, found that both *Agnikarma* and the combination therapy showed significant improvements, Group B (*Agnikarma+Panchatikta Guggulu*) yielded superior results in relieving stiffness, swelling, and restricted movement. This highlights the possible synergistic effect of combining non-pharmacological and pharmacological therapies in the management of OA. However, the study was limited by a small sample size, short follow-up duration, absence of a placebo or standard control group, open-label design, reliance on subjective outcome measures [10]. Similarly, several studies have demonstrated the potential of *Marma Chikitsa* in relieving pain and improving joint mobility. Mishra A and Shrivastava V conducted a clinical evaluation of *Marma Therapy* combined with *Janu Basti* in the management of *Janusandhigata Vata (OA of the Knee)*, showing significant improvement in pain, stiffness, and physical function scores ($p < 0.001$) [11].

Chaudhari P et al., conducted a case study evaluating the efficacy of *Marma Chikitsa* combined with shoulder exercises in the management of *Avabahuka*, which concluded the Combined *Marma Chikitsa+Shoulder exercises* demonstrated significant improvement in pain reduction, shoulder mobility, and overall function [12]. *Marma Chikitsa* is an effective non-pharmacological approach for knee joint pain, warranting comparative evaluation with *Agnikarma* in the present study [13].

Although the previously discussed studies focused on frozen shoulder [12,13], their relevance extends to knee OA, as both conditions are classified as *Vatavyadhi* involving *Sandhi*, *Snayu*, and *Asthi*, and share common clinical features such as pain, stiffness, and restricted mobility. The therapeutic principles and pain-modulating mechanisms of *Agnikarma* and *Marma Chikitsa* are consistent across different joints. However, a literature search revealed that there are limited randomised controlled trials directly comparing *Marma Chikitsa* and *Agnikarma* in knee OA. This highlights a significant research gap and underscores the need for

the present study to expand existing evidence and evaluate their role in knee joint pain management.

Therefore, the present study aimed to evaluate and compare the efficacy of *Marma Chikitsa* and *Agnikarma* in pain management of the knee joint.

Study Objectives

Primary Objectives:

1. To assess the efficacy of *Marma Chikitsa* in pain management of the knee joint.
2. To assess the efficacy of *Agnikarma* in pain management of the knee joint.

Secondary Objective:

1. To compare the efficacy of *Marma Chikitsa* and *Agnikarma* in pain management of the knee joint.

Hypotheses

Null Hypothesis (H_0): *Marma Chikitsa* will not be as effective as *Agnikarma* in the management of pain in the knee joint

Alternative Hypothesis (H_1): *Marma Chikitsa* will be as effective as *Agnikarma* in the management of pain in the knee joint.

MATERIALS AND METHODS

This study will be a randomised open-label equivalence clinical trial conducted at Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod (H), Wardha, Maharashtra, India from October 2024 to October 2026. The study has received approval from the Institutional Ethics Committee (Ref. No. MGACHRC/IEC/Jun-2024/851, dated 07/06/2024) and is registered under the Clinical Trials Registry of India (CTRI/2024/12/078562). Written informed consent will be obtained from all participants before enrolment.

Inclusion criteria:

- Informed consent;
- Patients aged between 30 and 50 years;
- Patients experiencing pain in the knee joint. Patients presenting with pain, stiffness, and restricted movement in the knee joint due to *Janusandhigata Vata* (OA of the Knee Joint).

Exclusion criteria: Patients will be excluded from the trial if they meet any of the following conditions:

1. A history of fracture or accidental trauma related to the knee joint.
2. Patients with *Alpa Satva* (low vitality) or *Avar Sahanam* (low pain tolerance).
3. Pregnant women.
4. Patients with chronic debilitating conditions such as:
 - Uncontrolled Diabetes Mellitus (DM).
 - Tubercular arthritis.

All participants will be counselled on lifestyle modifications, including joint-friendly exercises, dietary adjustments, and avoiding activities that aggravate knee pain [12].

Sample size calculation: Expected complete-remission proportions were assumed as $p_1=0.50$ for *Agnikarma* and $p_2=0.80$ for *Marma Chikitsa* [14] (based on prior clinical expectations).

Using the standard formula for two proportions:

$$n = \frac{[Z\alpha/2 \sqrt{2} p(1-p) + Z\beta \sqrt{p_1(1-p_1) + p_2(1-p_2)}]^2}{p}$$

$$p = (p_1 - p_2)^2$$

$$p = \frac{(0.50 + 0.80)}{2} = 0.65$$

$$2p(1 - p) = 2(0.65)(0.35) = 0.455$$

$$\sqrt{0.4550}=0.6742$$

$$p1(1 - p1) + p2(1 - p2)=0.25 + 0.16=0.41$$

$$\sqrt{0.41}=0.6403$$

$$1.96 \times 0.674=1.321$$

$$0.84 \times 0.640=0.538$$

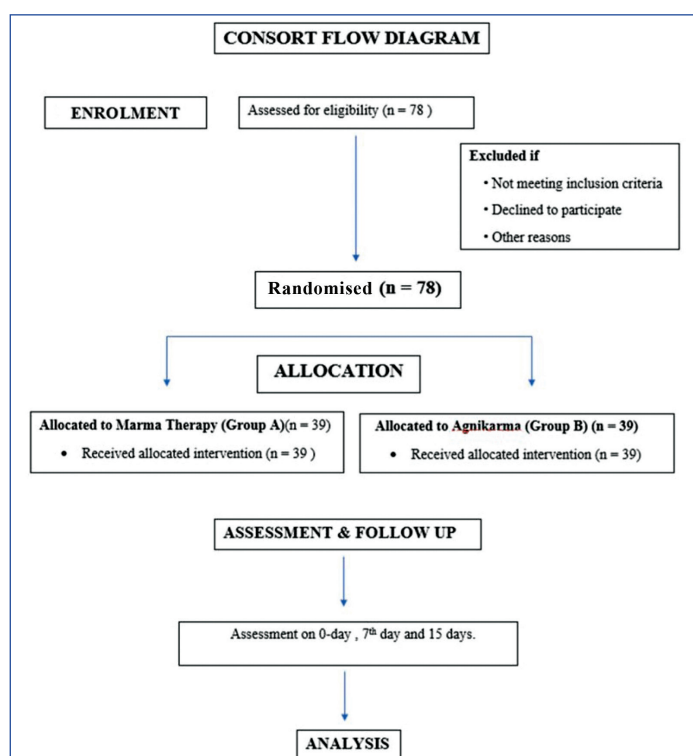
$$1.321 + 0.538=1.859$$

$$(p1 - p2)^2=(0.50 - 0.80)^2 = (-0.30)^2=0.09$$

$$n = \frac{(1.859)^2}{0.09}$$

$$= 38.4 \sim 39 \text{ per group.}$$

Therefore, 78 clinically diagnosed patients with knee joint pain will be included in the study, irrespective of gender, occupation, social status, or ethnicity. Patients will be divided into two groups: Group A (*Marma Chikitsa* group) and Group B (*Agnikarma* group), each comprising 39 patients as mentioned in [Table/Fig-1,2]. The allocation sequence will be created using computer-generated random numbers. The researcher or the first author will oversee the enrolment and assignment of participants to interventions. Clinical researchers or study coordinators will enrol participants, ensuring they meet inclusion criteria while remaining unaware of the allocation sequence. The research coordinator, blinded to the sequence, will assign participants to intervention groups using the pre-generated sequence. These steps will ensure an unbiased and transparent allocation process [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram showing the flow of participants through screening, randomisation, allocation, follow-up, and analysis. Baseline data, including demographic details and patient history, will be recorded.

Parameters	Group A (Study Group)	Group B (Control Group)
Sample size	39	39
Intervention	<i>Marma Chikitsa</i>	<i>Agnikarma</i>
Duration	Day 1 <i>Marma Chikitsa</i>	Day 1 <i>Agnikarma</i> procedure
	Day 7 <i>Marma Chikitsa</i>	Day 7 <i>Agnikarma</i> procedure
	Day 15 <i>Marma Chikitsa</i>	Day 15 <i>Agnikarma</i> procedure
Follow-up	Day 30	
Treatment duration	15 days	
Total study duration	30 days	

[Table/Fig-2]: Two groups: study group and control group with procedure timeline.

Group A (Study Group) Procedure of *Marma Chikitsa*

The patient will be positioned comfortably in a supine posture to allow optimal access to the lower limb *Marma* points. The designated *Marma* points *Janu*, *Urvi*, *Ani*, *Indrabasti*, and *Gulpha* [11] will be identified according to classical Ayurvedic anatomical landmarks. Each *Marma* point will be stimulated using firm, controlled pressure, 15-16 presses per point, with each press lasting approximately one second. This sequence of stimulation is performed three times, with a five-minute rest interval between each round to allow physiological recovery and ensure patient comfort [14]. The therapy will be administered on Day 1, Day 7, and Day 15 (three sessions over 15 days), followed by a follow-up assessment on Day 30, under the supervision of trained Ayurvedic specialists to maintain procedural accuracy and safety. The operation will be repeated after seven days to achieve the best therapeutic outcomes.

Group B (Control Group): *Agnikarma* Therapy

Participants in Group B will receive *Agnikarma* therapy for knee joint pain. The patient will be positioned comfortably in either a sitting or lying posture. The point of maximum tenderness on the knee is identified and marked. A copper *Agni Shalaka* is heated using a gas burner until it becomes red-hot. The heated *Shalaka* will be applied to the marked area in a dotted pattern, ensuring appropriate spacing between each touch. The procedure continues until signs of *Samyak Dagdha* (proper therapeutic cauterisation) will be observed immediately after the cauterisation, fresh aloe vera pulp will be applied to cool the area, reduce discomfort, and support healing.

Agnikarma will be performed once weekly for four weeks under expert supervision. Reassessments will be conducted after each session (Day 7 and Day 15), with a final evaluation on Day 30 to assess pain relief, functional improvement, and joint mobility. Both interventions will be repeated on Day 7 and Day 15, with reassessments conducted after each session. Follow-up evaluations will be performed on Day 30 to monitor pain relief, functional improvement, and joint flexibility [15].

Study Outcomes

Primary outcomes:

- Relief in Pain (Measured on the Visual Analogue Scale): Pain intensity will be assessed using the Visual Analogue Scale (VAS). Pain scores will be recorded at baseline (Day 0), Day 7, Day 15, and Day 30. Patients will be asked to rate their experience of pain using numbers from 0 (no pain) to 10 (Worst Pain) [16].
- The mean change from baseline to Day 30 will determine the primary efficacy of *Marma Chikitsa* and *Agnikarma* in managing knee pain.

Secondary outcomes:

Improvement in Range of motion (ROM) of the Knee Joint:

- Knee ROM will be measured using a standard universal plastic goniometer (Baseline® 360° Plastic Goniometer, Fabrication Enterprises Inc., USA), which is pre-calibrated and checked for zero error before each assessment [17]
- ROM measurements will be recorded at baseline and at the final follow-up to evaluate improvement in joint movement.

Walking performance:

- Functional mobility will be assessed by walking time over a fixed 20-metre distance.
- Two readings per assessment will be taken, with the average value to determine the final walking time [18].

Both the primary and secondary outcomes will be assessed at baseline and on 7th, 15th and 30th day.

Adverse Events (Safety)

Adverse Events (AEs) will be monitored at all study visits and recorded using a structured AE form. AEs will be graded as mild/moderate/severe. Participants will be withdrawn for severe reactions, infection, vasovagal syncope, or on request. Serious AEs will be reported to the Institutional Ethics Committee (IEC) within 24 hours.

STATISTICAL ANALYSIS

Statistical analysis will be performed using Statistical Package for the Social Sciences (SPSS) version 27 software; data will be expressed as mean±Standard Deviation (SD), and appropriate paired t-test and unpaired t-test will be applied. A p-value of <0.05 will be considered statistically significant.

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