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A Comparative Clinical Evaluation Of Sneha Yukta Janu Bandhana And Soft Knee Brace In The Management Of Janusandhigata Vata (Knee Osteoarthritis): A Randomized, Open-Label, Double-Arm Study Protocol

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ABSTRACT

Background: *Janusandhigata Vata*, described under *Vata Vyadhi* in *Ayurvedic* texts, is a degenerative condition of the knee joint characterized by pain (*Shoola*), swelling (*Shotha*), and crepitus (*Atopa*). It closely resembles osteoarthritis (OA) of the knee in modern medicine. Contemporary management includes NSAIDs and surgical interventions which may have adverse effects. Traditional *Ayurvedic* therapies such as *Sneha*, *Bandhana*, and *Moorchita Taila* application may offer non-invasive, cost-effective alternatives. **Objectives: Primary Objective:** To compare the efficacy of *Sneha Yukta Janu Bandhana* and soft knee brace in reducing *Janusandhi Shoola* (knee joint pain) in participants suffering from *Janusandhigata Vata* vis-à-vis osteoarthritis of the knee joint. **Secondary Objectives:** To compare the efficacy of *Sneha Yukta Janu Bandhana* and soft knee brace in reducing *Janusandhi Shotha* (swelling) in affected participants. To compare the efficacy of both interventions in reducing *Janusandhi Atopa* (crepitus) in participants. To evaluate the comparative effect of both interventions on functional disability using the WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) score. To assess and compare the improvement in Range of Motion (ROM) with onset of pain in the knee joint in both groups. **Materials and Methods:** This is an open-label, double-arm, randomized study. A total of 140 participants aged 40 – 70 years fulfilling diagnostic criteria for *Janusandhigata Vata* will be enrolled allocated randomly to one of the two study arms of 70 each. Group A is administered *Sneha Yukta Janu Bandhana* with *Moorchita Taila* for 12 hours daily for 14 days whereas Group B is administered a soft knee brace for 12 hours daily over the same period. Assessment was done using Visual Analogue Scale (VAS), WOMAC Index, range of motion (ROM), and clinical grading of *Janusandhi Shoola*, *Shotha*, and *Atopa* at baseline and after treatment. The outcomes are assessed at baseline and 15th day. **Results:** Post-treatment outcomes are expected to show statistically significant reduction in pain, swelling, crepitus, and improvement in joint function and ROM in Group A compared to Group B. The study aims to establish the superior efficacy of *Sneha Yukta Janu Bandhana* in managing degenerative knee disorders. **Conclusion:** The study is expected to validate the therapeutic potential of *Ayurvedic* intervention (*Sneha Yukta Janu Bandhana*) as an effective non-pharmacological treatment modality for *Janusandhigata Vata* and osteoarthritis of the knee joint.

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1. INTRODUCTION:

In *Ayurveda Vata Dosha* is considered the most important among the *Tridosha* as it governs all kinds of movement and functionality within the body. When aggravated *Vata* can lead to the vitiation of *Pitta* and *Kapha* as well resulting in complex pathological conditions.[1] One such condition is *Sandhigata Vata* which manifests when aggravated *Vata* localizes in the *Sandhi* (joints) particularly affecting the *Janu Sandhi* (knee joint) due to its constant usage and structural complexity.[2] *Janusandhigata Vata* is characterized by *Shoola* (pain) *Shotha* (swelling) *Atopa* (crepitus) and difficulty in movement. It is well described in classical texts such as *Charaka Saṃhitā, Suśruta Saṃhitā* and *Aṣṭāṅga Hṛdaya*. Suśruta has classified the *Janu Sandhi* as a *Vaikalyakara Marma* indicating its vital role in mobility and the debilitating nature of its disorders.[3] The progression of this condition is associated with *Dhatukṣhaya* and the predominance of *Vata* especially during old age.[4] The management of *Sandhigata Vata* in *Ayurveda* emphasizes *Snehana* (oleation) *Swedana* (sudation) *Bandhana* (bandaging) *Basti* (medicated enema) and internal medications. Among these *Snehana* combined with *Bandhana* plays a significant role in external therapies.[5] *Sneha Yukta Bandhana* provides warmth stability and nourishment to the *Sandhi* aiding in the pacification of *Vata Dosha*.[6] This external application helps in reducing pain and improving the functional mobility of joints. *Suśhruta* has described *Bandhana* as a supportive treatment modality for joint related disorders especially where *Vaikalyakara Marma* is involved.[7] The use of *Moorchita Taila* enriched with *Vata Shāmaka* properties in conjunction with bandaging has the potential to offer localized therapeutic effects by improving circulation reducing inflammation and strengthening the joint structures.[8] Traditional *Ayurvedic* treatments are increasingly gaining recognition for their low cost safe and holistic approach to chronic degenerative conditions. With the rising incidence of lifestyle and age-related musculoskeletal disorders therapies like *Sneha Yukta Janu Bandhana* not only align with the fundamental principles of *Vata Shamana* but also fulfill the demand for sustainable and non-invasive therapeutic options that can be integrated into outpatient *Panchakarma* practice. From a modern medical perspective osteoarthritis (OA) of the knee is a progressive degenerative joint disease affecting articular cartilage synovium and surrounding tissues.[9] It is a leading cause of pain and disability in older adults particularly in weight bearing joints such as the knees. Clinically it presents with pain joint stiffness crepitus swelling reduced ROM and functional limitation. The radiological hallmarks include joint space narrowing osteophyte formation and subchondral sclerosis.[10] The standard management of OA includes the use of NSAIDs corticosteroids physical therapy and joint replacement surgery in advanced stages along with non-pharmacological interventions like braces physical support devices and lifestyle modifications.[11] Hence exploring evidence based integrative approaches like *Sneha Yukta Janu Bandhana* may provide viable alternatives in managing knee OA with minimal adverse effects. *Sushruta* describes *Snehana* and *Bandhana* as therapeutic interventions, which may be adopted as a treatment protocol. The role of soft braces is well established and widely used in contemporary practice. As a low cost and accessible protocol, *Sneha Yukta Janu Bandhana* could serve as a non-pharmacological intervention to reduce pain and improve joint function in individuals suffering from knee osteoarthritis. Therefore, this study is intended to compare the efficacy of *Sneha Yukta Janu Bandhana* and soft knee brace in the management of *Janusandhigata Vata* vis a vis osteoarthritis of the knee joint.

OBJECTIVES:

Primary Objectives:

- To Compare the efficacy of *Sneha Yukta Janu* Bandhana and soft knee brace in reducing Janusandhi Shoola in participants suffering from Janusandhigata Vata vis-à-vis Osteoarthritis of Knee Joint

Secondary Objectives:

- To Compare the efficacy of *Sneha Yukta Janu* Bandhana and soft knee brace in reducing Janusandhi Shotha.
- To Compare the efficacy of *Sneha Yukta Janu* Bandhana and soft knee brace in the reducing Janusandhi Atopa.
- To Compare the efficacy of Sneha Yukta Janu Bandhana and soft knee brace in reducing Womac Score.
- To Compare the efficacy of *Sneha Yukta Janu* Bandhana and soft knee brace in improving Range of Motion (ROM) with Pain Onset.

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MATERIALS AND METHODS:

Study Design:
It is an open label double arm randomized study.

Study Setting:
A minimum of 140 participants presenting the *Lakshana* of *Janusandhigata Vata* visa vis osteoarthritis of knee joint coming under inclusion criteria are being screened and randomly selected from OPD and IPD of Indian Medical System, Shree Guru Govind Tricentenary University, Chandu, Budhera, Gurugram Haryana for the study.

Diagnostic Criteria:
- Participants presenting with *Lakshana* of *Janusandhigata Vata*
- Participants presenting with clinical features of osteoarthritis of knee joint
- Participants presenting with radiological evidence of osteoarthritis of knee joint

Inclusion Criteria:
- Participants of either gender who lie between the age group of 40 to 70 years
- Participants presenting with *Lakshana* of *Janusandhigata Vata*
- Participants presenting with signs and symptoms of osteoarthritis of knee joint
- Participants presenting with radiological evidence of osteoarthritis of knee joint

Exclusion Criteria:
- Participants having trauma to knee joint or any other systemic disorders which may interfere with the course of treatment
- Pregnant and lactating women

Intervention:
140 participants of *Janusandhigata Vata* visa vis osteoarthritis of knee joint who fulfil the inclusion criteria will be selected and randomly assigned into 2 groups namely Group A and Group B comprising 70 participants in each.

Group A - In this group *Sneha Yukta Janu Bandhana* with *Moorchita Taila* will be advised to the subjects. The affected knee joint of the subject will be exposed in sitting position with extended legs and *Mridu Abhyanga* with *Moorchita Taila* will be done followed by wrapping of *Cora* cloth roll soaked with warm *Moorchita Taila* around the knee joint in *Sama Bandhana* manner and tied with threads for 12 hours for 14 days.

Group B - In this group soft knee brace will be advised to the participants for 12 hours for 14 days.

Duration of the Treatment 14 Days

Withdrawal criteria:
Participants may be withdrawn from the study at their own request or at the discretion of the investigator. Participation in the study may be discontinued due to any serious adverse event that makes the participant unable to do the activities of daily living, Acute illnesses requiring hospitalization, worsening of symptoms during the course of the study, Participant not willing to continue the study.

Expected Outcomes:

Primary outcome measures:
- Change in the Value of VAS Score for Janu Sandhi Shoola
- **Secondary outcome measures:**
- Change in the 4-point grading scale of the Janu Sandhi Shotha
- Change in the 5-point grading scale of the Janu Sandhi Atopa
- Change in the value of WOMAC Score
- Change in the Value of Range of Motion with onset of pain.

Sample Size:
For a continuous endpoint comparing two independent groups, the sample size calculation is based on the difference between group means, desired significance level ($\alpha = 0.05$), and power (80%, $\beta = 0.2$). Given means of 4 and 2.5 for groups A and B respectively, with an absolute difference (Δ) of 1.5, and assuming known standard deviations, the required sample size per group is calculated using the formula incorporating critical Z-values for α (1.96) and β (0.84). The initial calculation yielded 63 participants per group, which was then adjusted for a 10% attrition rate, increasing the sample size to approximately 70 participants per group to ensure sufficient power despite potential dropouts.

Recruitment:
All the departments of the institute are informed about the study and eligibility criteria. A flyer with brief information about the study has been prepared and is placed on the hospital's notice board. Adequate numbers of patients with knee joint pain step in for Ayurveda treatment in the hospital so the target sample size is anticipated to be achieved in the defined timelines.

Assessment Criteria:
Assessment of the clinical study will be done based on the grading of subjective and objective parameters as per case *Proforma*.

Subjective Parameters
- *Janu Sandhi Shoola* pain in knee joint
- *Janu Sandhi Shotha* swelling in knee joint
- *Janu Sandhi Atopa* crepitus in knee joint
- WOMAC Score

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Objective Parameters - Range of motion ROM with pain onset using a goniometer.

Assessment Timeline:

- Pre-test before treatment on 0 day
- Post test after treatment on 15th day

Expected Outcomes:
Primary Outcome Measure

- Change in the value of VAS Score for *Janu Sandhi Shoola*

Secondary Outcome Measures

- Change in the four-point grading scale of *Janu Sandhi Shotha*
- Change in the five-point grading scale of *Janu Sandhi Atopa*
- Change in the value of WOMAC Score
- Change in the value of range of motion with onset of pain

Data Collection Methods:
Data collection for this clinical study will be conducted through both subjective and objective assessment methods, as outlined in the case proforma. Subjective parameters include *Janusandhi Shoola* (pain in the knee joint), *Janusandhi Shotha* (swelling in the knee joint), *Janusandhi Atopa* (crepitus in the knee joint), and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, which collectively provide insights into the patient's self-reported symptoms and functional status. Objective data will be gathered using a goniometer to measure the range of motion (ROM) of the knee joint, with attention to the point of pain onset, ensuring a standardized evaluation of joint mobility. Assessments will be conducted twice: initially before the commencement of treatment on day 0 (baseline) and subsequently on 15th day after treatment.

Data Management and Monitoring:
All data gathered through Case Report Forms (CRFs) and questionnaires from study participants is maintained with strict confidentiality and securely stored. Throughout the study period, regular data reviews and cleaning are performed to ensure accuracy and consistency. Upon completion of the study, the data will be anonymized prior to statistical analysis to protect participant identity. Since data entry is carried out in real-time alongside ongoing data verification, the likelihood of missing data is expected to be minimal. Any discrepancies or missing entries will be promptly addressed by cross-referencing with the original source documents.

Statistical Test:
For the Statistical analysis, the data obtained in the group were recorded and presented in tabulations and drawings. To infer the clinical study and to draw conclusion, the subjective parameters like *Janusandhi Shoola, Janusandhi Shotha, Janusandhi Atopa* and Womac Score will be subjected to Wilcoxon Signed Rank test for within the group analysis and Mann Whitney U test for between the groups analysis. The objective parameter like ROM will be subjected to Paired t-test for within the group analysis and independent t-test for between the groups analysis.

Adverse Events:
Any untoward medical occurrence that arises during treatment with a pharmaceutical product but does not necessarily have a causal relationship with this treatment.

Adverse Drug Reaction ADR:
A response which is noxious and unintended and which occurs at doses normally used in humans for prophylaxis diagnosis or therapy of disease or for modification of physiological function. An adverse drug reaction is characterized by the suspicion of a causal relationship between the drug and the occurrence that is judged as being at least possibly related to treatment by the reporting or reviewing health professional. Any adverse event observed during treatment or during follow up visits will be clearly documented using the ADR Form. Appropriate and timely management will be done in consultation with the physician or consultant associated in the trial. The investigating team will report the same to the ethics committee at the earliest.

DISCUSSION:

The concept of *Janusandhigata Vata* is elaborately discussed under *Vata Vyadhi* in classical *Ayurvedic* texts. In the *Charaka Samhita*, *Sandhigata Vata* is described as a condition where aggravated *Vata Dosha* localizes in the joints (*Sandhi*), leading to pain (*Shoola*), and restricted movement.[12] *Charaka* also mentions crepitus (*Atopa*) and functional disability as classical features of this condition. *Sushruta Samhita*, a foundational text in *Ayurveda*, identifies the *Janu Sandhi* (knee joint) as a *Vaikalyakara Marma*—a vital structure, injury to which results in deformity or functional loss. *Sushruta* further explains that wear and tear in the *Janu Sandhi* owing to aging and overuse leads to the manifestation of *Sandhigata Vata.*[13]

From a modern medical perspective, the condition that correlates closely with *Janusandhigata Vata* is osteoarthritis of the knee. As described in *Harrison's Principles of Internal Medicine*,

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osteoarthritis is a chronic degenerative joint disease primarily affecting articular cartilage and adjacent bone structures.[14] According to *Davidson's Principles and Practice of Internal Medicine*, osteoarthritis commonly affects weight-bearing joints and increases in prevalence with age. Radiological features such as joint space narrowing, osteophyte formation, and subchondral sclerosis are characteristic diagnostic findings.[15] *Harsh Mohan's Textbook of Pathology* elaborates on the pathophysiology, highlighting cartilage degradation, synovial inflammation, and biomechanical stress as core contributors to disease progression.[16]

Sushruta recommends *Bandhana* not only as a supportive and protective measure in trauma but also in degenerative conditions to maintain joint stability, reduce movement-induced aggravation of *Vata*, and support local healing. This technique, when combined with *Snehana* using medicated oils, becomes a powerful localized therapy for alleviating the condition.[17]

The use of *Moorchita Taila*, as described in *Bhaishajya Ratnavali*, highlights its therapeutic value in managing *Sandhigata Vata*. Enriched with *Vata Shamana*, *Shothahara*, and *Shulaprashamana* properties, this medicated oil, when applied with Abhyanga and Bandhana, provides targeted relief by improving circulation, reducing inflammation, and alleviating pain. The traditional processing methods enhance its efficacy, making it a valuable adjunct in Ayurvedic management of degenerative joint disorders like osteoarthritis.[18]

The current randomized controlled clinical study was conducted to evaluate and compare the efficacy of Sneha Yukta Janu Bandhana and a soft knee brace in the management of *Janusandhigata Vata* (osteoarthritis of the knee joint). The study builds upon both classical Ayurvedic wisdom and contemporary clinical understanding of osteoarthritis as a degenerative musculoskeletal condition.

Ayurveda advocates the use of external therapies like *Snehana* (oleation) and *Bandhana* (supportive wrapping) as core strategies in managing *Vata Vyadhi*. Sushruta's emphasis on protecting *Marma* structures form the conceptual foundation for Sneha Yukta Janu Bandhana, which combines both *Snehana* and supportive immobilization. This not only provides localized Vata pacification but also improves circulation and reduces mechanical strain on the joint.

Although soft braces are widely accepted in contemporary orthopedics for mechanical support and pain modulation, they often lack the therapeutic dimension inherent in Ayurvedic approaches. *Sneha Yukta Janu Bandhana*, on the other hand, may potentially delivers both structural support and pharmacological action through medicated oils like *Moorchita Taila*, which possess *Vata Shamana*, *Shothahara*, and *Shulaprashamana* properties.

Despite the known use of compression and bracing in both systems of medicine, there remains a dearth of clinical validation for Ayurvedic *Bandhana* techniques. This study, therefore, addresses a significant research gap by evaluating the holistic impact of an integrative therapy that aligns ancient wisdom with modern clinical endpoints. The therapy's accessibility, cost-effectiveness, and non-invasive nature will make it an ideal candidate for integration into outpatient Panchakarma practice, especially in geriatric and chronic care settings.

CONCLUSION:

The present clinical study is designed to evaluate and compare the efficacy of *Sneha Yukta Janu Bandhana* and soft knee brace in the management of *Janusandhigata Vata* visa vis osteoarthritis of the knee joint. Based on the classical *Ayurvedic* principles of *Snehana* and *Bandhana* and supported by contemporary understanding of joint stabilization and pain relief, *Sneha Yukta Janu Bandhana* using *Moorchita Taila* offers a promising non pharmacological, cost effective, and easily applicable therapeutic approach. Given the rising prevalence of osteoarthritis and the limitations of long-term conventional therapies, this study aims to provide evidence on the clinical utility of a traditional *Ayurvedic* intervention to reduce pain, swelling, stiffness, and improve joint mobility. The outcomes are expected to strengthen the integrative role of *Ayurveda* in managing degenerative musculoskeletal disorders.

TRIAL REGISTRATION:

This clinical trial is prospectively registered in the Clinical Trial Registry of India (CTRI/2025/04/083767).

ETHICAL STATEMENT:

The protocol is approved by the Institutional Ethics Committee of Faculty of Indian Medical System, SGT University, Gurugram, Haryana. (SGTUIFIMS/C1202S-31)

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Conflict of Interest: NIL

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