"Evaluation of efficacy of Tablet Babul (Acacia nilotica) versus Tablet Sallaki (Boswellia serrate) along with Abhyanga (external oleation therapy) in both groups in the management of Janusandhigata vata (Knee Osteoarthritis):Protocol for a Randomized Controlled Trial"

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Abstract

Background: Sandhigatavata (Osteoarthritis) develops as a result of vitiation of the Vata dosha. The most affected joint is Janusandhi (Knee joint). The symptoms include pain, swelling, and eventually dislocation and loss of function when vitiated Vata Dosha enters the joint. Babul (Acacia nilotica) has anti-osteoarthritic, analgesic, anti-inflammatory, and antioxidant effects.

Objective: 1. To evaluate the efficacy of Tab.Babulphalamajja with Abhyanga in the management of Janu Sandhigata Vata.
2. To evaluate the efficacy of Tab.Sallaki with Abhyanga in the management of Janu Sandhigata Vata.
3. To compare the efficacy of Tab.Babulphalamajja with Abhyanga and Tab.Sallaki with Abhyanga in the management of Janu Sandhigata Vata.

Methods: Total 160 patients will be divided in 2 equal groups, 80 in each. They will be treated with Babulphala tablet and Sallaki tablet along with Abhyanga in both groups for 30 days and assessed for Sandhishool (Joint pain), Sandhi vedana at the time of Akunchan and prasaran (pain during flexion and extension) , Sparshasahatwa (Tenderness), Sandhishotha (Joint swelling), Sandhi Graha (Stiffness), Vatapurna Drutisparsha (Crepitation), Walking Time, Range of movement of knee joint and Modified WOMAC index on day 15, 30, and 45.

Results: –Data will be collected by assessing subjective and objective criteria. Obtained data will be subjected to statistical analysis.

Conclusions: Conclusion will be drawn from the result obtained. Clinical Trial: Clinical trial registry with Trial REF/2022/12/061411

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CONSORT Flow Diagram

Screening of patients from OPD and IPD

Assessed for eligibility

Step I Enrollment

Inclusion Criteria -Classical Symptoms of OA as per ACR, Age 30 to 70 yrs of either sex, willing to give written consent

Exclusion Criteria 1. Known cases of Gout, rheumatoid arthritis, and psoriatic arthritis, trauma, fracture, deformity of knee, hip, back or gait, history of intra-articular injection, knee arthroscopy or knee replacement surgery. 2.Known cases of systemic disorders like Heart diseases, hepatic disorders, Renal disease, Cancer, Uncontrolled Diabetes mellitus, Autoimmune diseases, Tuberculosis , Atherosclerosis, Pulmonary dysfunction, HIV and other major health problems. 3.Pregnant and Lactating women

Randomized Controlled Allocation

Step II Allocation

Control Group (n= 80) Sallaki tablet 600mg BD

Study Group (n=80) Babulphalamajja tablet 500mg BD

Abyanga with Sesame oil in both groups

Step III Follow-Up

Follow up- During Treatment -On Day 15, 30 After treatment -Day 45

Follow up- During Treatment -On Day 15, 30 After treatment -Day 45

Step IV Analysis

Analysed (n=80)

Analysed (n=80)