

Efficacy of an Ayurvedic Formulation for Mild-to-moderate Osteoarthritis: A Phase 3, Randomized Controlled Study.

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Abstract

Context • Current treatment options offer only symptomatic pain relief for patients with osteoarthritis (OA). Thus, a need exists for effective treatment of the disability-causing disease. The proprietary polyherbal formulation, Nartana (Jointade), has been used for several years for OA.

Objective • The study intended to compare the benefits of the herbal formulation with those of routinely used nonsteroidal anti-inflammatory drugs (NSAIDs) for patients with mild-to-moderate OA.

Design • The research team designed a phase 3, double-blind, double-dummy, randomized controlled study. **Setting** • The study was conducted at 2 hospital sites in Pune, India. **Participants** • The participants were 80 outpatients with OA at the hospitals. **Intervention** • The participants were randomly assigned to receive either the intervention (herbal formulation) or the active control (diclofenac) for 12 wk. The herbal formulation group received 450 mg of Nartana (Jointade) capsule and diclofenac-matching placebo. Treatment was given 2 x/d for first 15 d and then 1 x/d until the end of the study. The control group received 50 mg of diclofenac tablet 2 x/d for first 15 d and then 100 mg of diclofenac tablet 1 x/d and a Nartana (Jointade) - matching placebo until end of the study.

Outcome Measures • To measure efficacy, the study used the modified Center for Rheumatic Diseases Pune version of the Western Ontario and McMaster Universities OA index (WOMAC) and the Health Assessment Questionnaire (HAQ). The study also measured overall perceived pain relief. The primary outcome measure was the change in the combined WOMAC score from baseline to postintervention (12 wk). Safety and other efficacy measures were the secondary end points.

Results • The herbal formulation and diclofenac groups matched well at baseline for demographic profile, disease status, and WOMAC scores. The combined WOMAC scores were significantly reduced from baseline to postintervention for both groups ($P < .01$). The earliest significant reduction was seen at week 4 ($P < .01$) and persisted at subsequent visits ($P < .01$). Similar changes were also seen in the WOMAC subscales-pain, stiffness, and physical function or difficulty in performing routine activities-and HAQ scores. Similar changes were also seen in the WOMAC subscales-pain, stiffness, and physical function or difficulty in performing routine activities-and HAQ scores. Improvement was also observed with perceived pain relief. Overall, the efficacy of the herbal formulation was not inferior to the diclofenac. Related adverse events were generally mild to moderate in nature and were resolved with or without symptomatic treatment.

Conclusions • For patients with mild-to-moderate OA, Nartana (Jointade) significantly reduced joint pain, stiffness, and physical function; improved quality of life; and provided pain relief. The herbal formulation's efficacy was not inferior to routinely prescribed diclofenac. The drug should be explored further in large long-term comparative studies as an alternative to NSAIDs.