

Double-Blind, Randomized, Controlled, Pilot Study Comparing Classic Ayurvedic Medicine, Methotrexate, and Their Combination in Rheumatoid Arthritis

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JCR: Journal of Clinical Rheumatology: June 2011 - Volume 17 - Issue 4 - p 185-192

doi: 10.1097/RHU.0b013e31821c0310

Original Articles

Abstract Author Information

Objective: To compare classic Ayurveda, methotrexate (MTX), and their combination in a double-blind, randomized, double-dummy, pilot trial in rheumatoid arthritis (RA) for 36 weeks.

Methods: Forty-three seropositive RA patients by American College of Rheumatology (ACR) criteria with disease duration of less than 7 years were assigned to the following treatment groups: MTX plus Ayurvedic placebo (n = 14), Ayurveda plus MTX placebo (n = 12), or Ayurveda plus MTX (n = 17). Outcomes included the Disease Activity Score (DAS28-CRP), ACR20/50/70, and Health Assessment Questionnaire - Disability Index. All measures were obtained every 12 weeks for 36 weeks. Analyses included descriptive statistics, analysis of variance, χ^2 , or Student *t* test. The unique features of this study included the development of placebos for each Ayurvedic pharmacological dosage form and individualization of Ayurvedic therapy.

Results: All groups were comparable at baseline in demographics and disease characteristics. There were no statistically significant differences among the 3 groups on the efficacy measures. ACR20 results were MTX 86%, Ayurveda 100%, and combination 82%, and DAS28-CRP response were MTX -2.4, Ayurveda -1.7, and combination -2.4. Differences in adverse events among groups were also not statistically significant, although the MTX groups experienced more adverse event (MTX 174, Ayurveda 112, combination 176). No deaths occurred.

Conclusions: In this first-ever, double-blind, randomized, placebo-controlled pilot study comparing Ayurveda, MTX, and their combination, all 3 treatments were approximately equivalent in efficacy, within the limits of a pilot study. Adverse events were numerically fewer in the Ayurveda-only group. This study demonstrates that double-blind, placebo-controlled, randomized studies are possible when testing individualized classic Ayurvedic versus allopathic treatment in ways acceptable to western standards and to Ayurvedic physicians. It also justifies the need for larger studies.

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This study was supported by an award from the National Center for Complementary and Alternative Medicine, by a National Institutes of Health grant 1 R21 AT-01969, and by the Ayurvedic Trust, Coimbatore, India.

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