Methotrexate for ankylosing spondylitis
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Authors' objectives
Background: Ankylosing spondylitis (AS) is a chronic inflammatory disease of unknown cause, characterized by sacroiliitis and spondylitis. Methotrexate (MTX), a widely used disease-modifying antirheumatic drug (DMARD), is effective for rheumatoid arthritis (RA), and so might work for AS. This is an update of a Cochrane review first published in 2004, and previously updated in 2006. Objectives: To evaluate the benefits and harms of MTX for treating AS.


Selection criteria: Randomized controlled trials (RCTs) and quasi-randomized controlled trials (qRCTs) examining the benefits and harms of MTX versus placebo, other medication, or no medication for treatment of AS.

Data collection and analysis: Two review authors independently extracted data and assessed risk of bias. We resolved any disagreements through discussions with a third review author. In the absence of significant heterogeneity, we combined results for continuous data using mean difference or standardized mean difference values. We calculated the risk ratio for dichotomous data.

Main results: We identified three RCTs (no additional new studies), which included 116 participants. Of these three trials, one was a 12-month trial that compared naproxen plus MTX with naproxen alone. Also, there were two 24-week trials that compared different doses of MTX with placebo. We included the outcomes of response, physical function, pain, spinal mobility, peripheral joints/entheses pain, swelling and tenderness, changes in spine radiographs, and patient and physician global assessment. We judged only one trial to be at low risk of bias. Across these three trials, we did not identify any statistically significant differences favoring MTX treatment over no MTX treatment apart from one exception. The response rate in one trial showed a statistically significant absolute benefit of 36% and a number to treat for benefit (NNT) of three in the MTX group compared to the placebo group (RR 3.18, 95% CI 1.03 to 9.79). This response rate was based on a composite index that included assessments of morning stiffness, physical well-being, Bath ankylosing spondylitis disease activity index (BASDAI), Bath ankylosing spondylitis functional index (BASFI), health assessment questionnaire for spondyloarthropathies (HAQ-S), and physician and patient global assessment. We did not identify any outcome that showed a statistically significant difference between the MTX treated and no MTX treatment groups when endpoint results were compared. Furthermore, no serious side effects were reported in any of the included trials.

Authors' conclusions: There is not enough evidence to support any benefit of MTX in the treatment of AS. High-quality RCTs of larger sample sizes are needed to clarify the effect(s) of MTX on AS. US: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004524.pub4/abstract

Bibliographic details
Chen Junmin, Veras Mirella MS, Liu Chao, Lin Junfang. Methotrexate for ankylosing spondylitis. Cochrane Database of Systematic Reviews: Reviews 2013; Issue 2

AccessionNumber
10000004524

Date abstract record published
13/07/2012

Record Status
This is an abstract for a Cochrane review