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Randomized Controlled Trial Int Immunopharmacol. 2014 Aug;21(2):468-73.

doi: 10.1016/j.intimp.2014.06.001. Epub 2014 Jun 11.

# Therapeutic efficacy of infused molecular hydrogen in saline on rheumatoid arthritis: a randomized, double-blind, placebo-controlled pilot study

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PMID: 24929023 DOI: 10.1016/j.intimp.2014.06.001

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#### **Abstract**

The aim of this study was to demonstrate the safety and efficacy of H2-saline infusion for treatment of rheumatoid arthritis (RA). We conducted a randomized, double-blind, placebo-controlled investigation of the infusion of 1 ppm H2-dissolved saline (H2-saline) in 24 RA patients. Patients were randomized 1:1 to receive 500 ml of either H2-saline or placebo-saline, which was drop infused intravenously (DIV) daily for 5 days. The disease activity score in 28 joints (DAS28) was measured at baseline, immediately post infusion, and after 4 weeks. Therapeutic effects of H2-saline on joint inflammation were estimated by measuring serum biomarkers for RA, tumor necrosis factor- $\alpha$  (TNF $\alpha$ ), interleukin-6 (IL-6), matrix metalloproteinase-3 (MMP-3), and urinary 8-hydroxydeoxyguanosine (8-OHdG). In the H2-infused group, average DAS28 decreased from 5.18  $\pm$  1.16 to 4.02  $\pm$  1.25 immediately post infusion and reached 3.74 ± 1.22 after 4 weeks. No significant decrease in DAS28 was observed in the placebo group throughout the study. IL-6 levels in the H2 group significantly decreased in 4 weeks by 37.3  $\pm$  62.0% compared to baseline, whereas it increased by 33.6  $\pm$  34.4% in the placebo group.  $TNF\alpha$  levels did not change remarkably in the H2 or placebo groups in 4 weeks post-infusion compared to baseline. The relative ratio of 8-OHdG in the H2 group also significantly decreased by 4.7%. After 4 weeks, MMP3 was significantly reduced by 19.2% ± 24.6% in the H2 group, and increased by 16.9% ± 50.2% in the placebo group. Drop infusion of H2 safely and effectively reduced RA disease activity.

**Keywords:** H(2)-Saline; IL-6; MMP-3; Molecular hydrogen; Reactive oxygen species; Rheumatoid arthritis.

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