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OXFORD ACADEMIC

Rheumatology (Oxford). 2006 Jan;45(1):50-2. Epub 2005 Nov 9.

Preliminary assessment of the efficacy, tolerability and safety of a cannabis-based medicine (Sativex) in the treatment of pain caused by rheumatoid arthritis.

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Abstract

OBJECTIVES: To assess the efficacy of a cannabis-based medicine (CBM) in the treatment of pain due to rheumatoid arthritis (RA).

METHODS: We compared a CBM (Sativex) with placebo in a randomized, double-blind, parallel group study in 58 patients over 5 weeks of treatment. The CBM was administered by oromucosal spray in the evening and assessments were made the following morning. Efficacy outcomes assessed were pain on movement, pain at rest, morning stiffness and sleep quality measured by a numerical rating scale, the Short-Form McGill Pain Questionnaire (SF-MPQ) and the DAS28 measure of disease activity.

RESULTS: Seventy-five patients were screened and 58 met the eligibility criteria. Thirty-one were randomized to the CBM and 27 to placebo. Mean (S.D.) daily dose achieved in the final treatment week was 5.4 (0.84) actuations for the CBM and 5.3 (1.18) for placebo. In comparison with placebo, the CBM produced statistically significant improvements in pain on movement, pain at rest, quality of sleep, DAS28 and the SF-MPQ pain at present component. There was no effect on morning stiffness but baseline scores were low. The large majority of adverse effects were mild or moderate, and there were no adverse effect-related withdrawals or serious adverse effects in the active treatment group.

CONCLUSIONS: In the first ever controlled trial of a CBM in RA, a significant analgesic effect was observed and disease activity was significantly suppressed following Sativex treatment. Whilst the differences are small and variable across the population, they represent benefits of clinical relevance and show the need for more detailed investigation in this indication.

Comment in

The use of a cannabis-based medicine (Sativex) in the treatment of pain caused by rheumatoid arthritis. [Rheumatology (Oxford). 2006]

PMID: 16282192 DOI: 10.1093/rheumatology/kei183

[Indexed for MEDLINE]