

Selvarajah D, Emery CH et al. Randomized Placebo-Controlled Double-Blind Clinical Trial of Cannabis-Based Medicinal Product (Sativex) in Painful Diabetic Neuropathy. Diabetes Care 2010; 33(1):128-130.

Design: Randomized clinical trial

Brief summary of results:

- 30 patients (19 men, 11 women, mean age 56) treated for painful diabetic neuropathy at a diabetes research facility in the UK
- Patients had a neuropathy total symptom score greater than 4 and less than 16, with stable glycemic control (HbA1c <11%), with at least 6 months of neuropathic symptoms despite an adequate trial of antidepressants
- Sativex or placebo were administered sublingually for 12 weeks, 2 weeks for titration and 10 weeks for maintenance
- There were no differences between Sativex and placebo for changes in total pain score from baseline to the final week of treatment
- Quality of life scores improved in both groups, but there were no between-group differences
- Patients with higher baseline depression scores were more likely to respond to treatment (Sativex or placebo) than non-depressed patients

Authors' conclusions:

- Sativex was not superior to placebo for treatment of diabetic painful neuropathy
- Depression is a potential confounder, and future Sativex trials should screen entrants for depression
- There was a considerable placebo response, which may have obscured the effect, if any, of Sativex

Comments:

- Several critical pieces of information are lacking or sketchy: method of randomization, allocation concealment, entry and exclusion criteria, and the number of patients randomized to each treatment group
- The study may have been underpowered; sample size calculation was not discussed

Assessment: Inadequate for any conclusions about the effectiveness of Sativex