

No strong evidence to back use of cannabis extract in multiple sclerosis

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There is no strong evidence to back the use of *cannabis* extract in the treatment of Multiple Sclerosis (MS), concludes a review of the available evidence on the first licensed preparation, published in the December issue of *Drug and Therapeutics Bulletin* (*DTB*).

Sativex, in the form of a mouth spray, contains the principal extracts—dronabinol and [cannabidiol](#)—found in the leaf and flower of the *cannabis* plant. It is the first cannabinoid preparation to be licensed for use in the treatment of muscle spasms in MS.

MS is estimated to affect around 60,000 people in England and Wales, and around one in every 1000 people will develop the condition in the UK.

An increase in [muscle tone](#), or spasticity is a common symptom of the condition, causing involuntary spasms, [immobility](#), disturbed sleep, and pain.

Complex combinations of drugs are sometimes needed to manage spasticity, but they don't work that well and have a range of unpleasant side effects.

Sativex is intended for use as a second line treatment in patients in whom these other options have failed. But the *DTB* review found that the trial data on which the success of Sativex is based, are limited.

Overall, the trials, on which the drug's approval was based, did show a small difference in the numbers of patients who in whom symptoms abated compared with those taking a dummy (placebo) preparation.

But in many of these studies, Sativex was used for relatively short periods—from six weeks to four months. And none included an [active ingredient](#) with which the effects of Sativex could be

compared.

Two of the trials included doses that exceeded the 12 daily sprays for which the preparation is licensed. One trial did not have sufficient numbers of participants to validate the results.

A third trial, which was properly designed, and did have sufficient numbers of participants, did not find any significant difference in [symptom relief](#) between those who took Sativex and those who didn't.

The preparation is also expensive, notes *DTB*, and costs around 10 times as much as other drugs used for the secondary treatment of MS [muscle spasms](#).

As yet, the body that advised the NHS on its use of treatments, the National Institute for Health and Clinical Excellence (NICE) has not offered any advice on the use of *cannabis* extract either, although it is set to do so.

But the *DTB* review says that the strength of the evidence is insufficient to warrant its routine use. "We believe that such limitations make it difficult to identify the place of this product in clinical practice," it concludes. Commenting on the review, GP and *DTB* editor, James Cave, said the findings of the review were "disappointing."

"MS is a serious and disabling condition, and it would be great to say that this drug could make a big difference, but the benefit is only modest," he said.

More information: What place for cannabis extract in MS? *DTB* Vol 50, No 12 December 2012

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