Multiple Sclerosis and Extract of Cannabis: results of the MUSEC trial

1. John Peter Zajicek, Jeremy C Hobart, Anita Slade, David Barnes, Paul G Mattison, on behalf of the MUSEC Research Group

Author Affiliations
1. Clinical Neurology Research Group, Peninsula College of Medicine and Dentistry, University of Plymouth, Derriford, UK
2. Department of Neurology, St George's Healthcare NHS Trust, London, UK
3. Multiple Sclerosis Service, Ayrshire Central Hospital, Irvine, Ayrshire, UK

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Abstract

Objective Multiple sclerosis (MS) is associated with chronic symptoms, including muscle stiffness, spasms, pain and insomnia. Here we report the results of the Multiple Sclerosis and Extract of Cannabis (MUSEC) study that aimed to substantiate the patient based findings of previous studies.

Patients and methods Patients with stable MS at 22 UK centres were randomised to oral cannabis extract (CE) (N=144) or placebo (N=135), stratified by centre, walking ability and use of antispastic medication. This double blind, placebo controlled, phase III study had a screening period, a 2 week dose titration phase from 5 mg to a maximum of 25 mg of tetrahydrocannabinol daily and a 10 week maintenance phase. The primary outcome measure was a category rating scale (CRS) measuring patient reported change in muscle stiffness from baseline. Further CRSs assessed body pain, spasms and sleep quality. Three validated MS specific patient reported outcome measures assessed aspects of spasticity, physical and psychological impact, and walking ability.

Results The rate of relief from muscle stiffness after 12 weeks was almost twice as high with CE than with placebo (29.4% vs 15.7%; OR 2.26; 95% CI 1.24 to 4.13; p=0.004, one sided). Similar results were found after 4 weeks and 8 weeks, and also for all further CRSs. Results from the MS scales supported these findings.

Conclusion The study met its primary objective to demonstrate the superiority of CE over placebo in the treatment of muscle stiffness in MS. This was supported by results for secondary efficacy variables. Adverse events in participants treated with CE were consistent with the known side effects of cannabinoids. No new safety concerns were observed.

Trial registration number NCT00552604.