

A multiple randomised controlled trial of cannabinoids on spasticity in multiple sclerosis (MS)

Submission date 23/10/2000	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/06/2015	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr John Zajicek

Contact details
Department of Neurology
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G9900990

Study information

Scientific Title

A multiple randomised controlled trial of cannabinoids on spasticity in multiple sclerosis (MS)

Study objectives

The hypothesis is that cannabinoids have a beneficial therapeutic effect on spasticity in MS, and may also have beneficial effects on pain, tremor, micturition disturbance and overall measures of quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions

Patients will be randomly assigned to one of four regimens in the ratio 2:1:2:1, as follows:

1. THC (Marinol) (maximum total daily dose 0.25 mg/kg in equal doses, given as 2.5 mg THC capsules)
2. Placebo capsules (containing oil vehicle) matched to appearance of THC
3. Natural cannabis oil (Cannador) containing the same dose of THC, made up to GMP standard
4. Placebo capsules (containing oil vehicle) matched to appearance of the cannabis capsules

Intervention Type

Other

Primary outcome measure

Changes in Ashworth score

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2000

Completion date

31/03/2003

Eligibility

Key inclusion criteria

1. Clinically definite or laboratory supported MS aged 18-64 years inclusive
2. Significant spasticity in at least 2 lower limb muscle groups (Ashworth score of 2 or more, in two or more muscle groups, eg left foot plantar flexion & left knee & right knee flexors, etc)
3. Stable disease for previous 6 months in the opinion of the treating physician
4. Antispasticity medication and physiotherapy stabilised for the last 30 days
5. Patients may be ambulatory or not

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

64 Years

Sex

Both

Target number of participants

660

Key exclusion criteria

1. Immunosuppression, including corticosteroids or interferon taken currently or in previous 30 days.
2. Past or present history of ischaemic heart disease or psychotic illness
3. Other serious illness likely to interfere with study assessment such as major organ failure, neoplasia, coeliac disease - see appendix 9 and if in doubt please contact the Plymouth Trial Coordinating Centre (PTCC) .
4. Open/ infected pressure sores or other source of chronic infection.
5. Significant fixed tendon contractures.
6. Severe cognitive impairment such that patient is unable to provide informed consent.
7. Women who are pregnant, lactating or not using adequate contraception.
8. Unwilling to stop driving or operating dangerous machinery for the study period and one week afterwards.

9. Cannabinoids taken currently or in previous 30 days.
10. Previous use of THC (Marinol) at any time.
11. Anticipated foreign travel within the first 15 weeks of the trial.
12. Anticipated immunisations within the first 15 weeks of the trial.
13. Participation in other research studies currently or within previous 3 months.
14. Other problems likely to make participation difficult at the discretion of the neurologist.

Date of first enrolment

01/12/2000

Date of final enrolment

10/10/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Derriford Hospital

Plymouth

United Kingdom

PL6 8DH

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/11/2003		Yes	No
Results article	follow up results at 12 months	01/12/2005		Yes	No