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

Submission date
23/10/2000

Recruitment status
No longer recruiting

Registration date
23/10/2000

Overall study status
Completed

Last Edited
12/06/2015

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Changes in Ashworth score

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
All

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

United Kingdom

England

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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