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Cannabinoids in progressive inflammatory brain disease (CUPID)

Submission date
03/05/2005

Recruitment status
No longer recruiting

Registration date
21/06/2005

Overall study status
Completed

Last Edited
13/04/2016

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis is the commonest cause of neurological disability in young adults, affecting around 100,000 people in the UK. Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along nerves. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks the myelin sheath, stripping it from the nerves (demyelination). This demyelination means that messages cannot travel along the nerves effectively causing a range of disabilities, including mobility problems, problems with thinking, learning and planning (cognitive function), vision, and speech and swallowing. Around 15% of people diagnosed with MS have the primary-progressive type (PPMS). This involves the progressive worsening of disability from the onset of symptoms, without any periods of recovery. Secondary-progressive MS (SPMS), also known as late stage MS, involves the progressive worsening of disability after a relapsing-remitting phase (characterised by periods where the symptoms are very mild or disappear completely). Currently, there are limited treatment options for the progressive types of MS. It has been reported that the active ingredient of cannabis (tetrahydrocannabinol, THC) could be helpful in treating MS symptoms. The aim of this study is to find out whether THC can help to slow or stop the progression of disability in patients with progressive MS.

Who can participate?
Adults with primary or secondary progressive MS.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive THC to take by mouth every day for six months. The dosage is calculated based on body weight, but can be a maximum of 28mg/kg. Those in the second group receive a placebo (dummy pill) to take every day for six months. Participants in both groups are followed up every six months for up to 36 or 42 months. At the follow up visits, the progression (worsening) of the disease is measured using physical evaluations and a walking test, to find out if it has had an effect on disability.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Peninsula Medical School (UK)

When is the study starting and how long is it expected to run for?
July 2005 to June 2011

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof John Zajicek
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Study website
http://www.pms.ac.uk/cnrg/cupid

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0500290

Study information

Scientific Title

The Cannabinoid Use in Progressive Inflammatory brain Disease (CUPID) trial

Acronym
CUPID

Study objectives
To test whether cannabinoids show any neuroprotective action in progressive multiple sclerosis (MS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Devon Research Ethics Committee (now Cornwall and Plymouth Research Ethics Committee), 28/02/2006, ref: 06/Q2103/1

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
Participants are randomly allocated to one of two groups in a 2:1 ratio (intervention:control)

Intervention group: Participants take a maximum of 28mg/day oral tetrahydrocannabinol (THC) for six months.
Control group: Participants take a placebo daily for six months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Tetrahydrocannabinol

Primary outcome measure
Added 17/07/09:
1. Physician-based EDSS: time to EDSS progression of at least one point from a baseline EDSS of 4.0, 4.5 or 5.0 or at least 0.5 points from a baseline EDSS ≥5.5. Once identified, deterioration must be confirmed at the next scheduled six monthly visit.
2. Change in Multiple Sclerosis Impact Scale-29 version 2 (MSIS-29v2) 20-point physical subscale (MSIS-29phys) score

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2005

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Primary/secondary progressive multiple sclerosis
2. Worsening disability
3. Age 18-65
4. EDSS score 4 to 6.5

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Immunodulation or immunosuppressive therapy
2. Steroids or cannabinoids recently

3. Psychotic illness
4. Cognitive impairment
5. Pregnancy

Date of first enrolment
01/07/2005

Date of final enrolment
30/06/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Peninsula Medical School
Plymouth
United Kingdom
PL6 8BX

Sponsor information

Organisation
Plymouth Hospitals NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) - G0500290

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	01/09/2013		Yes	No
Results article	results	01/02/2015		Yes	No