Cannabinoids in progressive inflammatory brain disease (CUPID)

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
03/05/2005		□ Protocol		
Registration date 21/06/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
13/04/2016	Nervous System Diseases			

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 primaryprogressive 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 John.zajicek@pcmd.ac.uk

Study website

http://www.pms.ac.uk/cnrg/cupid

Contact information

Type(s)

Scientific

Contact name

Prof John Zajicek

Contact details

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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

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)

Sponsor details

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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