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A functional magnetic imaging (fMRI) study of the effects of cannabis-based medicines (CMEs) on the neutral activity associated with noxious thermal stimulation in healthy human volunteers (CRI.FM024). Protocol V2. FINAL

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 02/11/2016	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0176131698

Study information

Scientific Title
A functional magnetic imaging (fMRI) study of the effects of cannabis-based medicines (CMEs) on the neutral activity associated with noxious thermal stimulation in healthy human volunteers (CRI.FM024). Protocol V2. FINAL

Study objectives
We wish to undertake an experimental study of the effects of cannabis-based medicines (CMEs) on the neutral activity associated with the experience of pain in healthy volunteer participants. Fifteen volunteers will complete an fMRI scanning protocol on 4 separate study days on each of which they will receive one of 3 CMEs or a placebo treatment. During the scanning protocol, volunteers will receive noxious thermal stimulation on the dorsum of the left hand. Differences in volunteers' ratings of the intensity of the pain experience, as well as differences in measures of neutral activity associated with this experience, will provide important new information about CMEs' putative analgesia and their underlying mechanisms.

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)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Sign and Symptoms: Pain

Interventions
15 volunteers will complete an fMRI scanning protocol on 4 separate study days on each of which they will receive one of 3 CMEs or a placebo treatment. During the scanning protocol, volunteers will receive noxious thermal stimulation on the dorsum of the left hand.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Volunteers' rating of pain during noxious thermal stimulation
2. BOLD response associated with thermal stimulation after the 3 CMEs treatments and the placebo treatment sessions.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2003

Completion date
31/10/2007

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Healthy volunteer

Age group
Not Specified

Sex
Not Specified

Target number of participants
15 healthy people

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2003

Date of final enrolment
31/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

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