

A functional magnetic imaging (fMRI) study of the effects of cannabis-based medicines (CMEs) on the neural 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

Protocol serial number
N0176131698

Study information

Scientific Title

A functional magnetic imaging (fMRI) study of the effects of cannabis-based medicines (CMEs) on the neural 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 neural 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 neural 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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/10/2007

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

University of Oxford
Oxford
United Kingdom
OX3 7JX

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration