Investigating the acute effects of THC on functional brain systems

Published: 18-01-2007
Last updated: 08-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Psychiatric disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON30656

Source
ToetsingOnline

Brief title
THC-phMRI

Condition

- Psychiatric disorders NEC

Synonym
addiction, schizophrenia, substance abuse

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: TI Pharma

Intervention

Keyword: acute effects, cannabis, pharmacological MRI, THC

Outcome measures

Primary outcome

The main study parameter is the blood-oxygen-level dependent (BOLD) signal.

Secondary outcome

Further, behavioral parameters and the concentration of plasma THC and its main

metabolites will be obtained.

Study description

Background summary

Cannabis is by far the most frequently used illicit drug worldwide. The use of cannabis is associated with a variety of neuropsychiatric diseases, like addiction and schizophrenia. Elucidating the effects of cannabis on the brain is therefore of significant importance.

Study objective

The main objective of this study is to determine whether THC, the primary psychoactive ingredient in cannabis, modulates activity in functional brain systems. We test this by assessing the acute effects of THC on the reward system, the working memory system and the associative memory system.

Study design

The study consists of a randomized, double-blind, placebo-controlled pharmacological MRI experiment. The study takes up two test days, on which subjects receive either placebo or THC by means of a vaporizer. On a test day subjects undergo three sessions of obtaining MRI scans. During each session, subjects will perform one of the following tasks: a reward task, a working memory task and an associative memory task. A fourth session includes the performance of neuropsychological tests. At the beginning of every session subjects receive a new dose of THC or placebo.

Study burden and risks

In this study the burden is especially formed by the administration of THC. However, the risk is small, mainly because of the fact that the subjects have been screened extensively and that they have experience with the effects of cannabis. Nevertheless, THC could induce some adverse effects. Therefore heart rate and behavioral effects will be monitored during the whole experiment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* History of mild cannabis use for at least one year (<1/week and <=>4/year)
* History without psychotic experiences after cannabis use

* Age between 18 and 45 years
* Right-handedness, assessed with the Edinburgh Handedness Inventory
* Written informed consent of the subject

Exclusion criteria

* Any clinical significant abnormality of any clinical laboratory test, including drug screening
* Impaired physical health evaluated by medical history, physical (including neurological) examination and screening laboratory tests
* History of clinically significant psychiatric or neurological illness
* History of clinically significant psychiatric or neurological illness in first- or second-degree relatives
* History of alcohol and/or drug abuse (DSM-IV criteria)
* Body Mass Index (B.M.I.) <18 kg/m2 or >28 kg/m2
* Paranoid ideation or psychoticism on SCL-90
* Any subject who received any investigational medication within 90 days prior to the start of the study or who is scheduled to receive an investigational drug
* The use of any medication within three weeks prior to the start of the study, except for paracetamol
* Positive HIV or Hepatitis B/C test
* Blood donation within 3 months before the start of the study
* Claustrophobia
* Metal objects in or around the body (braces, pacemaker, metal fragments)

Study design

Design

Study phase:	2
Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2008

Enrollment:	21
Type:	Actual

Ethics review

Approved WMO Date:	18-01-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-07-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-10-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-12-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-07-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-07-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-09-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2006-004482-33-NL
CCMO	NL14098.041.07