Investigating the acute effects of THC on functional brain systems

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22844

Source
NTR

Brief title
THC-fMRI in healthy volunteers

Health condition

no condition, healthy person.

Sponsors and support

Primary sponsor: University Medical Centre Utrecht
Source(s) of monetary or material Support: TI Pharma

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Behavioral parameters (two sets of visual analogue scales), cerebral blood flow (measured

with Arterial Spin Labeling), the concentration of plasma THC and its main metabolites, and the performance on neuropsychological tests will be measured.

Study description

Background summary

Cannabis is by far the most frequently used illicit drug worldwide. THC, the main psychoactive component in cannabis, exerts its effects via CB1 cannabinoid receptors. CB1 receptors are abundantly expressed in the striatum, the hippocampus, and the frontal cortex. These brain regions are involved in reward, associative memory, and working memory, respectively. Therefore, the main objective of this study is to determine whether THC modulates activity in these functional brain systems. The study is a randomized, double-blind, placebo-controlled pharmacological MRI experiment. It consists of 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 objective

Inhalation of delta9-THC will modulate activity in functional brain systems, including the reward system, the working memory system and the associative memory system.

Study design

Functional MRI scans will be obtained between 7 and 21 minutes after inhalation. Behavioral parameters will be measured and blood samples will be withdrawn before and after functional MRI.

Intervention

Healthy subjects will inhale placebo or 6 mg THC, the main psychoactive ingredient of cannabis, four times by means of a Volcano® vaporizer. Inhalation takes 1 - 2 minutes.

Contacts

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Eligibility criteria

Inclusion criteria

1. History of mild cannabis use for at least one year (<1/week and ¡Ý 4/year)

2. History without psychotic experiences after cannabis use

3. Age between 18 and 45 years

4. Right-handedness, assessed with the Edinburgh Handedness Inventory (Oldfield, 1971

5. Written informed consent of the subject

Exclusion criteria

1. Any clinical significant abnormality of any clinical laboratory test, including urinary drug screening

2. Impaired physical health evaluated by medical history, physical (including neurological) examination and screening laboratory tests

3. History of clinically significant psychiatric or neurological illness

4. History of clinically significant psychiatric or neurological illness in first- or second-degree relatives

5. History of alcohol and/or drug abuse (DSM-IV criteria)

6. Body Mass Index (B.M.I.) <18 kg/m2 or >28 kg/m2

7. Paranoid ideation or psychoticism on SCL-90

8. 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

9. The use of any medication within three weeks prior to the start of the study, except for paracetamol

10. Positive HIV or Hepatitis B/C test

11. Blood donation within 3 months before the start of the study

12. Claustrophobia

13. Metal objects in or around the body (braces, pacemaker, metal fragments)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-03-2008
Application type:	First submission

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
NTR-new	NL1160
NTR-old	NTR1204
Other	METC Utrecht : 06-269
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A