Investigating the acute effects of THC on functional brain systems

Gepubliceerd: 03-03-2008 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22844

Bron
NTR

Verkorte titel
THC-fMRI in healthy volunteers

Aandoening

no condition, healthy person.

Ondersteuning

Primaire sponsor: University Medical Centre Utrecht
Overige ondersteuning: TI Pharma

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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 Behavioral parameters will be measured and blood samples will be withdrawn before and after functional MRI.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2008
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1160
NTR-old	NTR1204
Ander register	METC Utrecht : 06-269
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A