The Role of the Endocannabinoid System in Psychiatric Disorders and Symptoms: a Pharmacological fMRI study.

Gepubliceerd: 29-04-2009 Laatst bijgewerkt: 13-12-2022

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

Samenvatting

ID

NL-OMON20111

Bron
NTR

Verkorte titel
THC-phMRI in patients

Aandoening

psychiatric disorders (schizophrenia, addiction, OCD, ADHD, depression), fMRI, THC, cannabinoid system

Ondersteuning

Primaire sponsor: Prof. Dr. N.F. Ramsey
Overige ondersteuning: Top Institue Pharma (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

Extensive research has identified and characterized an endocannabinoid system in the human central nervous system. It consists of cannabinoid receptors and endocannabinoids that work on the receptors. Recently, the endocannabinoid system has been associated with several psychiatric disorders, such as schizophrenia, depression and addiction. This system provides a novel potential target for medical treatment of these disorders. This study assesses the role of the endocannabinoid system in symptoms of psychiatric disorders. THC, which is the main psychoactive constituent of cannabis, works on cannabinoid receptors as an agonist. The study is a randomized, double-blind, placebo-controlled pharmacological MRI experiment in which healthy controls will be compared to patients with a psychiatric disorder. The study consists of two test days, on which subjects receive either placebo or THC by means of a vaporizer. On a test day subjects will perform three cognitive tasks, during which functional MRI scans will be measured. Also, a series of neuropsychological tests will be performed. Before every task subjects receive a new dose of THC or placebo.

Doel van het onderzoek

The endocannabinoid system is involved in cognitive functioning, and therefore, challenging this system with THC will influence cognitive processing in humans. Moreover, subjects with cognitive impairments (i.e. psychiatric patients) will react differently on a cannabinoid challenge than healthy controls.

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. Two testdays are performed (one day placebo, one day THC), two weeks apart.

Onderzoeksproduct en/of interventie

1. THC will be inhaled (5 times: first dose 6 mg, upload doses 1 mg) by means of a Vulcano Vaporizer;

2. Functional MRI scans will be performed during cognitive tasks.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy control or Diagnosed with one psychiatric disorder, according to DSM-IV criteria, axis I:

A. Schizophrenia;

B. Depression;

C. ADHD;

D. Addiction to nicotine (heavy smokers);

E. OCD.

2. Male;

3. Current occasional cannabis use since at least one year (<1/week and ¡Ý 4/year) without known negative implications (e.g. bad trip, cannabis-induced psychosis);

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. Clinical significant abnormalities, except for the predetermined psychiatric disorder;

2. For healthy controls, first degree relatives with a psychiatric disorder according to DSM IV;

3. Impaired physical health evaluated by medical history and physical (including neurological) examination;

4. Current diagnosis of abuse of drugs or alcohol (according to DSM-IV) except for tobacco;

5. Past but recent diagnosis of abuse of drugs or alcohol other than tobacco, i.e. within 12 months preceding study inclusion;

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

7. 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;

8. The use of any medication within three weeks prior to the start of the study, except for paracetamol and medication for the psychiatric disorder;

9. Blood donation within 3 months before the start of the study;

10. Claustrophobia;

11. 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 gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-04-2009
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	NL1685
NTR-old	NTR1787
Ander register	METC Utrecht : 07/371
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A