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

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON20111

**Source**
NTR

**Brief title**
THC-phMRI in patients

**Health condition**

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

### Sponsors and support

**Primary sponsor:** Prof. Dr. N.F. Ramsey
**Source(s) of monetary or material Support:** Top Institue Pharma (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

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.

### Study objective

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.

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

### Intervention

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.

# Contacts

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# Eligibility criteria

## Inclusion criteria

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.

### Exclusion criteria

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).

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |

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| Masking: | Double blinded (masking used) |
| Control: | Placebo |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-02-2009 |
| Enrollment: | 120 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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| Date: | 29-04-2009 |
| 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 | NL1685 |
| NTR-old | NTR1787 |
| Other | METC Utrecht : 07/371 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**
N/A