

# The role of the endocannabinoid system in Attention-Deficit/Hyperactivity Disorder and symptoms: a pharmacological fMRI study

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To establish if and how the endocannabinoid system is involved in ADHD and related symptoms. This will be investigated by assessing the acute effects of a cannabinoid agonist (THC) on brain function related to ADHD and ADHD symptoms.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Psychiatric disorders NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON35106

### Source

ToetsingOnline

### Brief title

THC phMRI in ADHD patients

### Condition

- Psychiatric disorders NEC

### Synonym

ADHD, Attention-Deficit/Hyperactivity Disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** subsidie van Top Instituut Pharma

## Intervention

**Keyword:** ADHD, endocannabinoid system, pHMRI, THC

## Outcome measures

### Primary outcome

The primary outcome measure of the study is the

Blood-Oxygenation-Level-Dependent (BOLD)-signal, measured with fMRI

### Secondary outcome

Behavioral parameters (reaction time, accuracy) during performance of the tasks in the scanner and during performance of the neuropsychological tests.

Melatonin levels in saliva

Bloodplasma levels of THC and its main metabolites

## Study description

### Background summary

The endocannabinoid system is involved in many processes in the brain. It exists of endocannabinoid receptors and endogenous ligands (endocannabinoids) acting on these receptors. (Abnormalities in) the endocannabinoid system are linked to ADHD-related symptoms like sleep onset disorders and cognitive impairments (attention deficits, impulsivity, reward system). Pharmacological neuroimaging may contribute in our knowledge on the role of the endocannabinoid system in ADHD.

### Study objective

To establish if and how the endocannabinoid system is involved in ADHD and related symptoms. This will be investigated by assessing the acute effects of a cannabinoid agonist (THC) on brain function related to ADHD and ADHD symptoms.

### Study design

Randomized, double-blind, placebo-controlled pharmacological fMRI study, involving two study days on which participants either receive placebo or THC by use of a vaporizer. On each study day subjects undergo a scanning session, during which they perform three computer tasks. Prior to each task subjects are administered a new (upload)dose of THC or placebo. After the scan session, subjects perform a neuropsychological test battery.

## **Study burden and risks**

De toediening van THC vormt de belangrijkste belasting voor de deelnemers. Het risico is echter gering omdat:

- \* er een relatief lage dosering wordt gebruikt
- \* de deelnemers uitgebreid zijn gescreend
- \* de deelnemers zelf ook incidenteel cannabis gebruiken en dus bekend zijn met de effecten.

Desondanks kan THC enige ongewenste effecten veroorzaken (angst, paranoia). De subjectieve, gedragsmatige en fysiologische effecten (hartslag, bloeddruk) worden daarom gedurende het hele experiment nauwlettend gemonitord.

The main burden for subjects participating in this study will be the THC administration. The risk, however, is small because:

- \* a relative low dose of THC is used
- \* subjects are screened thoroughly
- \* subjects are incidental cannabis users and, therefore, are familiar with the effects of cannabis

Nevertheless, THC could induce some adverse effects (anxiety, paranoia). Therefore, subjective, behavioral and physiological effects (heartrate, blood pressure) will be monitored tightly during the whole experiment.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

- \* Diagnosed with ADHD (DSM-IV criteria)
- \* History of mild cannabis use for at least one year (less than once/week and more than 4 times / year)
- \* Right-handedness, assessed with the Edinburgh Handedness Inventory
- \* Written informed consent of the participant

### **Exclusion criteria**

- \* Any clinical significant abnormality of any clinical laboratory test, except for the predetermined psychiatric disorder, i.e. ADHD, including urinary screening
- \* Impaired physical health evaluated by medical history, physical (including neurological) examination and screening laboratory tests (see par 8.3.1.)
- \* history of alcohol and /or drug abuse (DSM-IV criteria)
- \* Body Mass Index (B.M.I) < 18 kg/m<sup>2</sup> or > 28 kg/m<sup>2</sup>
- \* 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
- \* use of any medication within three weeks prior to the start of the study, except for paracetamol and medication for ADHD and related symptoms
- \* contra-indications for MRI (claustrophobia, metal objects in body (e.g. braces, pacemakers, metal clips)

## **Study design**

## Design

Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	15-06-2010
Application type:	First submission
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**

EudraCT

CCMO

**ID**

EUCTR2009-017944-15-NL

NL30979.041.09