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.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Psychiatric disorders NEC
Study type	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 efffects (anxiety, paranoia). Therefore, subjective, behavioral and physiological effects (heartrate, blood pressure) will be monitored tightly during the whole experiment.

Contacts

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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/wek 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/m2 or > 28 kg/m2
* 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	ID
EudraCT	EUCTR2009-017944-15-NL
CCMO	NL30979.041.09