Brain kinetics of neurotransmission during THC intoxication

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In this study, we want to know more about the acute effects of cannabis on neurotransmitter systems. For this, we compare the effects of cannabis with the effects of placebo in 50 healthy participants, both occasional and chronic users. During and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50329

Source ToetsingOnline

Brief title

Brain kinetics of neurotransmission during THC intoxication

Condition

• Other condition

Synonym

n.a.

Health condition

veranderingen in de hersenen

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Kinetics, magnetic resonance spectroscopy, Neurotransmission, THC

Outcome measures

Primary outcome

Neurotransmission of glutamate, GABA and dopamine, farmacokinetics of THC and

subjective drug experiences.

Secondary outcome

n.a.

Study description

Background summary

Chronic use of cannabis can cause changes in the brain, leading to drug dependence. These brain changes are mainly related to neurotransmitter systems. At this time, however, little is known about the changes in the brain that occur during drug use.

Study objective

In this study, we want to know more about the acute effects of cannabis on neurotransmitter systems. For this, we compare the effects of cannabis with the effects of placebo in 50 healthy participants, both occasional and chronic users. During and after the administration of cannabis and placebo, the acute changes in brain chemicals will be mapped by means of brain scans.

Study design

Double-blind, placebo-controlled 2-way crossover design in which healthy cannabis users (30 occasional and 20 chronic users) will participate. On two separate test days placebo and cannabis will be administered in the scanner, and their brain activity will be recorded. In addition, blood samples will be taken at regular intervals, cognitive performance will be measured and subjects will fill in questionnaires about their drug use and subjective experiences.

Intervention

Placebo and bedrobinol (300 microgram/kg bodyweight)

Study burden and risks

The subjects will inhale placebo and Bedrobinol , in a cross-over study. The subjects will be in a scanner for maximally 1.5 hours. Blood samples are taken at regular intervals throughout the test day.

Contacts

Public Universiteit Maastricht

Universiteitssingel 40 Maastricht 6229 ER NL **Scientific** Universiteit Maastricht

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

3 - Brain kinetics of neurotransmission during THC intoxication 2-05-2025

Inclusion criteria

*Occasional users:Used cannabis between 1 times a month and 1 times a week during the previous year

*Chronic users: Used cannabis at least 3times/week during the previous year *Age between 18 and 40 years

*Free from psychotropic medication

*Good physical health as determined by medical examination and laboratory analysis

*Absence of any major medical, endocrine and neurological condition

*Normal weight, body mass index between 18 and 28 kg/m2

*Written Informed Consent

Exclusion criteria

*History of drug abuse (other than the use of cannabis) or addiction (determined by the medical questionnaire, drug questionnaire and medical examination)
*Pregnancy or lactation
*Hypertension (diastolic> 90; systolic> 140)
*Current or history of psychiatric disorder (determined by the medical

questionnaire and medical examination)

*Liver dysfunction

*(Serious) side effects to previous cannabis use

History of cardiac dysfunctions (arrhythmia, ischemic heart disease,)

*For women: no use of a reliable contraceptive

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2014
Enrollment:	62
Туре:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bedrobinol
Generic name:	dronabinol/THC
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Date:	28-07-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	08-10-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	14-11-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	19-11-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	29-03-2017
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	20-04-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	20-04-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	18-05-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2014-002977-12-NL
ССМО	NL49896.068.14