Cannabis as a cause of psychosis: An ecogenetic study linking cannabis-induced dopamine response to psychotic mechanisms and experiences

Published: 23-05-2008
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The following research questions are formulated:A. Does exposure to cannabis (THC) result in an increased dopamine response in the striatum (as measured with PET)? And does cannabis use lead to an increase in psychotic experiences or symptoms?B. Do...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational invasive

Summary

ID

NL-OMON33989

Source
ToetsingOnline

Brief title
Acute effects of cannabis on dopamine response in the brain

Condition

- Schizophrenia and other psychotic disorders

Synonym
schizophrenia and psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: NWO en Universiteit Maastricht

Intervention

Keyword: cannabis, dopamine, psychosis

Outcome measures

Primary outcome

(i) Dopamine response after THC and placebo

(ii) Psychotic experiences in response to THC and placebo as measured with i)

computer-assisted tasks and ii) clinical interviewing

Secondary outcome

(i) genotype (on the basis of DNA analyses)

Study description

Background summary

Cannabis use is considered to be an environmental factor that contributes to the risk of developing psychosis. Individuals with a certain genetic vulnerability seem to be particularly sensitive to the psychotic effects of cannabis. However, the biological mechanism that underlies this relation remains unknown.

Study objective

The following research questions are formulated:

A. Does exposure to cannabis (THC) result in an increased dopamine response in the striatum (as measured with PET)? And does cannabis use lead to an increase in psychotic experiences or symptoms?

B. Do genetic factors exert an influence on the effects of THC on dopamine and psychotic experiences?

Study design

The study makes use of a placebo-controlled single-blind design.

Intervention

Participants will be asked to inhale THC and placebo in one session and to subsequently undergo a PET scans. In addition they will be asked to undergo a total of 1 MRI scan.

Study burden and risks

Healthy participants may temporarily experience psychotomimetic effects. Patients may temporarily experience worsening of psychotic symptoms. For both groups these effects will only be transient, lasting maximal 200 minutes.
The study will approximately take 8 hours within a range of two weeks.

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

18-50 years of age
life-time use of cannabis without having experienced negative effects
BMI between 18.5 and 27
diagnosis of schizophrenia according to DSM-IV (only patients)
having given informed consent (written and orally)

Exclusion criteria

head trauma
severe renal or liver dysfunction
alcohol use in excess of 5 units per day
weekly use of illicit drugs (other than cannabis)
pregnancy
breast-feeding
personal or family history of psychosis or use of antipsychotic medication (only valid for healthy participants who are no first degree relatives of patients with schizophrenia)

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2009
Enrollment:	45
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[18F]fallypride
Generic name:	[18F]fallypride
Product type:	Medicine
Brand name:	delta-tetrahydrocannabinol (THC)
Generic name:	delta-tetrahydrocannabinol (THC)

Ethics review

Approved WMO Date:	23-05-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-07-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-10-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-02-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-12-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	

Date:	30-12-2009
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	EUCTR2008-001964-35-NL
CCMO	NL22847.068.08