The effects of THC on dopamine release.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24587

Source
Nationaal Trial Register

Brief title
THC-PET study

Health condition

Positron Emission Tomography (PET), raclopride, Tetrahydrocannabinol (THC), cannabis, dopamine

Sponsors and support

Primary sponsor: Department of Psychiatry
University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

After inhalation of THC, dopamine release will be investigated using the [11C]raclopride displacement paradigm. Increase in striatal synaptic dopamine will be measured by the decline in D2 receptor availability to the binding of [11C]raclopride. This binding will be demonstrated using Positron Emission Tomography (PET).

Secondary outcome

Behavioral parameters (BPRS and two VAS questionnaires) and the concentration of plasma THC and its main metabolites will be obtained as well. Vital signs (blood pressure and heart rate) will be measured regularly.

Study description

Background summary

Background
Animal models demonstrate that the primary psychoactive ingredient of cannabis, Ä9-THC, is able to release dopamine in the striatum, which is part of the mesolimbic dopamine system. It is well known that the functioning of this system is disturbed in both addiction and schizophrenia. However, human data concerning THC and dopamine release are limited. Therefore in this pilot study we will investigate the effects of THC on the human mesolimbic dopamine system.

Hypothesis
Inhalation of Ä9-THC will stimulate dopamine release in striatum and its sub-regions.

Design
This is a double-blind, randomized, placebo-controlled study. Seven healthy, mild cannabis users between 18 and 45 years old will receive placebo or 8 mg THC by means of a vaporizer on two separate occasions. Dopamine release will be investigated using the [11C]raclopride displacement paradigm: increase in striatal synaptic dopamine will be measured by the decline in D2 receptor availability to the binding of [11C]raclopride. This binding will be demonstrated using Positron Emission Tomography (PET).

Study objective

Inhalation of Delta9-THC will stimulate dopamine release in striatum and its sub-regions.

Intervention

Healthy subjects will inhale placebo or 8 mg of THC, the main psychoactive ingredient of cannabis, by means of a vaporizer.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 18 and 45 years;
2. History of mild cannabis use for at least one year (<1/week and => 4/year);
3. History without further illicit drug use;
4. History without psychotic experiences after cannabis use;
5. Written informed consent of the subject.

Exclusion criteria

1. Any clinical significant abnormality of any clinical laboratory test, including drug screening;
2. Impaired physical health evaluated by medical history, physical (including neurological) examination and screening laboratory tests;
3. Any major current psychiatric diagnosis on axis-1 of DSM-IV;
4. History of clinically significant psychiatric or neurological illness;
5. History of clinically significant psychiatric or neurological illness in first- or second-degree relatives;
6. History of alcohol and/or drug abuse (DSM-IV criteria);
7. Paranoid ideation or psychoticism on SCL-90;
8. 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 drugs;
9. The use of any medication within three weeks prior to the start of the study, except for paracetamol;
10. Positive HIV or Hepatitis B/C test;
11. Blood donation within 3 months before the first test day;
12. Hb must be => 8 mmol / liter (males) or => 7 mmol / liter (females);
13. Body Mass Index (B.M.I.) between 18 and 28 kg/m2;

14. Claustrophobia;
15. Metal objects in or around the body (braces, pacemaker, metal fragments);
16. Pregnancy and breast feeding;
17. Exposure to radioactivity leading to a yearly cumulative dose of 10 mSv or more.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2006
Enrollment:	7
Type:	Actual

Ethics review

Positive opinion

Date:	15-06-2006
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	NL645
NTR-old	NTR706
Other	: N/A
ISRCTN	ISRCTN61445818

Study results

Summary results
N/A