The effects of tetrahydrocannabinol on dopamine release

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
21/07/2006		☐ Protocol		
Registration date 21/07/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
08/01/2021	Nervous System Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers NL645, NTR706

Study information

Scientific Title

The effects of tetrahydrocannabinol on dopamine release

Acronym

THC-PET study

Study objectives

Inhalation of delta9-tetrahydrocannabinol (THC) will stimulate dopamine release in striatum and its sub-regions

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised, double-blind, placebo-controlled, crossover trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

No condition, healthy person

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Tetrahydrocannabinol

Primary outcome measure

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 measures

Behavioral parameters (brief psychiatric rating scale [BPRS] and two visual analogue scale [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.

Overall study start date

01/08/2006

Completion date

31/12/2006

Eligibility

Key inclusion criteria

- 1. Aged between 18 and 45 years
- 2. History of mild cannabis use for at least one year (<1 per week and >=4 per year
- 3. History of no further illicit drug use
- 4. History of no psychotic experiences after cannabis use
- 5. Written informed consent of the subject

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Both

Target number of participants

7

Total final enrolment

7

Key exclusion criteria

- 1. Any clinically 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 Diagnostic and Statistical Manual of Mental Disorders (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 Symptom checklist-90 (SCL-90)
- 8. Any subject who has received any investigational medication within 90 days prior to the start of the study or who is scheduled to receive any investigational drugs
- 9. The use of any medication within three weeks prior to the start of the study, except for paracetamol
- 10. Positive human immunodeficiency virus (HIV) or hepatitis B or hepatitis C test
- 11. Blood donation within three months before the first day of test
- 12. Haemoglobin (Hb) must be =>8 mmol per liter (males) or =>7 mmol per liter (females)
- 13. Body mass index (BMI) between 18 and 28 kg/m^2
- 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

Date of first enrolment

01/08/2006

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre
University Medical Center Utrecht (UMCU)
Utrecht

Netherlands 3584 CX

Sponsor information

Organisation

University Medical Center Utrecht (UMCU), Department of Psychiatry (The Netherlands)

Sponsor details

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Sponsor type

University/education

ROR

https://ror.org/0575yy874

Funder(s)

Funder type

University/education

Funder Name

VU University Medical Center

Funder Name

University Medical Center Utrecht (UMCU)

Funder Name

Centre for Human Drug Research (CHDR), Leiden

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2009	08/01/2021	Yes	No