ISRCTN61445818 https://doi.org/10.1186/ISRCTN61445818

The effects of tetrahydrocannabinol on dopamine release

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)
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Sponsor information

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

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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