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Influence of Genetics on the Degradation of Cannabinoids

Submission date	Recruitment status	[_] Prospectively registered
22/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/06/2025	Other	

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
THLD2010-1

Study information

Scientific Title
Genetic Influence of CYP2C9 Polymorphism on Pharmacokinetics of intravenously applied d-9-Tetrahydrocannabinol (THC) in Healthy Volunteers

Study objectives
Rate of intravenous applied d-9THC depends on genetically determined CYP2C9, where two polymorphisms (SNP) are known

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee of Bern approved on the 22nd of February 2010 (ref: KEK-Number 241/09)

Study design
Single centre open label uncontrolled interventional pharmacokinetic study

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pharmacokinetics, Forensic Medicine, Anesthesiology

Interventions
300 healthy volunteers will be genetically screened for single nucleotide polymorphisms (SNP) in the Cytochrome P450 2C9 (CYP2C9) gene. The three alleles identified for this study will be
1. Wild Type (WT)
2. R144C
3. I359L

30 volunteers will be picked to form 6 groups will be based on the 6 possible allelic combinations; 11 12 13 22 23 33. Each group consists of about 5 people, although there may be

some differences due to allelic frequencies. We will not study more than 30 volunteers. If more than 5 persons in a specific group are available from the screened population (that is expected for the WT), than we will randomly choose by computer randomisation.

Participants will receive a single dose of 0.1mg/kg intravenous (IV) THC. Vitals and blood THC levels will be measured continuously for 72 hours.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
d-9-Tetrahydrocannabinol (THC)

Primary outcome measure
Blood levels of THC and degradation products, assessed by blood sampling at baseline, and 1, 2, 5, 10, 15, 20, 30, 45, 60, 90, 180, 300 Minutes and 24h, 48h after THC injection.

Secondary outcome measures
1. Vitals
2. Side effects
3. Well being, assessed by questionnaires filled out at regular intervals as well by Visual Analogue Scale (VAS)
4. Pupillometry will obtained in a subgroup using standardised techniques

Overall study start date
01/03/2010

Completion date
01/07/2010

Eligibility

Key inclusion criteria
1. Healthy volunteers
2. 18-65 years old

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Screening: 300, Inclusion in Study: 30

Key exclusion criteria
1. Refusal to participate
2. Does not speak or read German
3. Ongoing smoking status (<3 months since quitting)
4. Extreme nutritive status (BMI outside 16-35)
5. American Society of Anesthesiologists Status Class III and above
6. Suspected coronary heart disease
7. Major heart rhythm disturbances
8. Liver enzymes P450 altering medication
9. Any treated or suspected psychiatric diseases at any time during lifetime. This includes, but is not restricted to schizophrenic disorders, depression, use of heroin, cocaine, LSD, and ongoing use of THC (<1 month since quitting).
10. Pregnant, women will be tested by urine Human Chorionic Gonadotropin (HCG)-stick

Date of first enrolment
01/03/2010

Date of final enrolment
01/07/2010

Locations

Countries of recruitment
Switzerland

Study participating centre
University Dept of Anesthesiology and Pain Therapy
Bern
Switzerland
3010

Sponsor information

Organisation
Inselspital (Switzerland)

Sponsor details
c/o Prof. Robert Greif - Vice-Chair
University Dept of Anesthesiology and Pain Therapy

Inselspital
Bern
Switzerland
3010

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01q9sj412

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Inselspital (Switzerland) - University Dept of Anesthesiology and Pain Therapy, Departmental Research Fund

Funder Name
Federal Office of Public Health (BAG) (Switzerland) (unrestricted grant)

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	Quantification and time course of subjective psychotropic and somatic effects	18/12/2024	19/12/2024	Yes	No
Results article	Effects on pupillary reaction and pupil size	13/05/2025	06/06/2025	Yes	No