

# Influence of Genetics on the Degradation of Cannabinoids

<b>Submission date</b> 22/02/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/06/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**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), then 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?
<a href="#">Results article</a>	Quantification and time course of subjective psychotropic and somatic effects	18/12/2024	19/12/2024	Yes	No
<a href="#">Results article</a>	Effects on pupillary reaction and pupil size	13/05/2025	06/06/2025	Yes	No