Alcohol and cannabis.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20338

Source
NTR

Brief title
N/A

Health condition

Cognitive functions in frequent cannabis users

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University

Intervention

Outcome measures

Primary outcome

To determine the pharmacokinetic and pharmacodynamic parameters of THC in combination with alcohol as a function of time.

Secondary outcome

N/A

Study description

Background summary

In this study we will investigate whether there is cross tolerance for the effects of alcohol and cannabis. Therefore we will investigate both the pharmacodynamic and pharmacokinetic effects of a combined administration of cannabis and alcohol.
Randomized, double-blind, placebo controlled, 3-way cross-over design.

1. 21 volunteers, age between 18 and 40, will be randomly assigned to a treatmentorder;

2. There are 3 test days in this study, on which the subject will be administered alcohol. After this the alcohol level will be kept constant by giving small repeated doses of alcohol. 2,5 hours after the first alcohol administration, the cannabis sigaret will be smoked. In between test days, there will be a wash out period of at least 7 days;

3. Before inclusion, a medical screening will take place. Also a training of the different tests will take place;

4. On each test day different cognitive test will be administered to the subjects. A first time after administration of alcohol, and two times after smoking the cannabis sigaret. Furthermore, 11 blood samples and 12 saliva samples will be taken at different times during each test day.

Study objective

It is hypothesized that in the population of frequent cannabis users, cross tolerance will have developed for the effects of alcohol, and that therefore the behavioral effects after alcohol will be less when given in combination with cannabis.

Study design

The test battery will be repeated three times, up to 7 hours after alcohol administration and 4 hours after cannabis smoking.

Pharmacokinetic samples will be taken app. every 30 minutes after cannabis smoking.

Intervention

Cannabis (400 µg/kg bodyweight THC) in combination with alcohol to reach 0,0, 0,5 and 0,8 mg/ml BAC.

Contacts

Public
E.L. Theunissen
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Scientific
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Maastricht
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Eligibility criteria

Inclusion criteria

1. Free from psychotropic medication;

2. Good physical health as determined by medical examination and laboratory analysis (Appendix 1);

3. Absence of any major medical, endocrine and neurological condition;

4. Normal weight, body mass index (weight/length2) between 18 and 28 kg/m2;

5. Written Informed Consent;

6. To check whether subjects are high experienced users, a blood sample from the screening will be tested. THC in blood has to be >= 3,5 ng/ml;

7. Participants are smokers with a maximum of 25 cigarettes/day.

Exclusion criteria

1. History of drug abuse or addiction (other than the use of cannabis);

2. Pregnancy or lactation;

3. Excessive drinking (> 21 alcoholic consumptions a week);

4. No experience with alcohol;

5. Excessive smoking (>25 cigarettes/day);

6. Hypertension (diastolic> 100; systolic> 170);

7. Current or history of psychiatric disorder;

8. Color-blindness;

9. Dyslexia.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	21
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-06-2009
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	NL1730
NTR-old	NTR1840
Other	MEC MUMC : 09-3-018
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A