A study into the combined effects of alcohol and cannabis on cognitive performance in high experienced cannabis users

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33124

Source
ToetsingOnline

Brief title
Alcohol and cannabis

Condition

- Other condition

Synonym
cognitive functioning in cannabis users

Health condition

cognitieve disfunctie

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: alcohol, cognitive performance, pharmacokinetics, THC

Outcome measures

Primary outcome

The primary outcome of the study is to determine the pharmacokinetic and pharmacodynamic parameters of THC in combination with alcohol as a function of time. The Divided Attention Task will be the primary cognitive task and THC concentration in serum will be used as primary pharmacokinetic value.

Secondary outcome

niet van toepassing

Study description

Background summary

Cannabis is the most widely used drugs in the Western world. As cannabis is used this often, and because it is probable that the therapeutic use of cannabis will increase, it is important to study the effects of cannabis on different functions even further. Cannabis is often used in combination with other drugs, such as alcohol, therefore in this study the combination of the two drugs will be examined.

Study objective

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.

Study design

Randomized, double-blind, placebo controlled, 3-way cross-over design.
- 21 volunteers, age between 18 and 40, will be randomly assigned to a treatmentorder
- 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.
- Before inclusion, a medical screening will take place. Also a training of the different tests will take place.
- 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.

Intervention

The amount of alcohol that will be administered will be calculated using a formula. The aim is to reach a blood alcohol concentration of 0,0, 0,5 or 0,8 on the three seperate testdays. the cannabis sigaret will contain 400 µg THC per kg bodyweight. The lenght of the sigaret en the amount of alcohol will be determined for each subject individually, based on his/her bodyweight.

Study burden and risks

The total time investment for the subjects will be about 25 hours. First a medical screening will take place, in which a physical exam will be done, including a blood (10ml) and urine sample. The subject will come 3 times to the trial site for the test days. Each testday will last about 7,5 hours. During each test day, a cognitive testbattery will be repeated three times. Furthermore 11 blood samples (8ml each) will be taken. In order to minimize the burden for the subjects, bloodsampling will be done by inserting a canula. Also 12 saliva samples will be taken. Therefore subjects will have to chew on an absobent cotton for 1 minute.
In the night before each testday, subjects have to have a good nights rest. Also they are not allowed to use any alcohol or caffeïne 24 hours before each testday. There are no risks related to this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Good health, age between 18 and 40, experience with cannabis (with a minimum of 1 year, and 200 times a year), written informed consent

Exclusion criteria

use of other drugs
Pregnancy or lactation
no experience with alcohol

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-07-2009
Enrollment:	21
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bedrobinol
Generic name:	Dronobinol/THC
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	22-04-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	15-06-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR27516.068.09-NL
CCMO	NL27516.068.09