Alcohol calibration study to establish limits for fitness to drive.

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The aim is to establish substantiated limit values based on the results of this study for tests used to determine driving ability in another study conducted with Cat. III drug users.

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

Summary

ID

NL-OMON42508

Source
ToetsingOnline

Brief title
Alcohol calibration and driving fitness

Condition

- Other condition

Synonym
n.a.

Health condition

het betreft gezonde vrijwilligers die alcohol toegediend krijgen

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Infrastructuur en Milieu
Source(s) of monetary or material Support: Ministerie van Infrastructuur en Milieu

Intervention

Keyword: alcohol, calibration, driving fitness, limits

Outcome measures

Primary outcome

The primary outcome measure in this study is the Standard Deviation of Lateral Position (SDLP, in cm) of the Highway Driving test conducted on public roads.

Secondary outcome

The secondary outcome measures will be the results on the following cognitive tests:

- Trailmaking A en B
- Digit Symbol Substitution Test
- Adaptive Tachistoscopic Traffic Perception Test (ATTPT)
- Reaction Test
- Determination Test
- Vienna Risk-Taking Test Traffic
- Psychomotor Vigilance Taak
- Driving simulator tests (Swingdrive (fixed en free speed), Intersections, Merging, Vigilantie-SDLP)

Study description

Background summary

The Dutch assessment of driving ability with the use of potentially dangerous drugs when driving refers to the classification of thet International Council on Alcohol, Drugs and traffic Safety (ICADTS). Medications are categorized in class I (safe to drive), class II (be carefull when driving) and class III (do

not drive).
This classification is mainly based on double-blind research in healthy subjects using the medication only once, or just briefly. There is, however, insufficient knowledge of everyday effects in chronic users of these drugs. The Netherlands has a large number of chronic users of ICADTS class III drugs. It is very likely that the majority of these ambulatory patients also drives the car.
Being able to determine when a patient is fit to drive despite the use of class III drugs has major social and economic benefits. Both for the user who then is fully mobile, but also for society because there is possibly a group of users that is wrongly declared unfit to drive. If it turns out that they still can participate in traffic they are better employable in the labor market and less dependent on others to meet their mobility needs.
Currently, the limit values for the driving ability of the aforementioned Cat. III drug users are being established (Protocol number NL47435.068.13, EudraCT number 2013-004936-31).
The research proposed in this protocol to the legal limit of alcohol (e.g. BAC 0.5 mg / ml) on drive ability serves as a reference for the above-mentioned study on the limits for the fitness to drive of the aforementioned Cat. III drug users.
Conducting neuropsychological tests, letting people drive in a simulator and on the public highway, after administration of a dose of alcohol that results in a BAC of up to 0.5 mg / ml and comparing the results on these tests with the performance when they are not under the influence of alcohol (eg after placebo), will create a basic standard. It will be possible to compare the test results against the performance on the same tests by users of Cat. III drugs in another study.

Study objective

The aim is to establish substantiated limit values based on the results of this study for tests used to determine driving ability in another study conducted with Cat. III drug users.

Study design

In addition to a training day, there will be a double-blind randomized trial of two test days, in which alcohol (BAC 0.5 mg / ml) or placebo-alcohol is administered.

Intervention

Alcohol (amount related to sex, age, size and weight, in order to achieve a BAC of 0.5 mg/ml) and placebo-alcohol.

Study burden and risks

There are for participants no benefits to expect from participation. Except that they will be compensated for their participation with an amount of 120 euros plus travel expenses.
The disadvantages to the subject are:
1. The time they spend with participation in the research and medical examinations. Each volunteer comes to the test center three times. A time for a training and twice for a test day. Each day takes about 5 hours.
2. In addition, some participants can get simulator sickness while driving in the simulator (similar to motion sickness). This is told in advance and they will be closely monitored while driving. It is made clear that they can stop the investigation at any time.
There are no anticipated risks to participants in this study. For the following reasons
1. Only healthy volunteers will be enrolled.
2. The administered dose of alcohol is relatively low and participants are accustomed to drink this amount of alcohol in everyday life. We therefore expect no serious adverse events during their participation.

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

- A BMI between 19 and 29 m2/kg (BMI Classification. Global Database on Body Mass Index. World Health Organization. 2006)
- Minimum 5 years in possession of a valid driving license
- Minimal driving experience of on average 3,000 km/year
- Sufficient visual acuity (defined as a score of at least 0.5 on the SnellenCard).
- Age from 23 to 75 years. The lower age limit is set at 23 years, so there no participants with an initial drivers license are included. The legal alcohollimit is actually lower for the initial license (0.2 instead of 0.5 per mille per mille). The upper limit is set at 75 years, since over 75 years the risk of neurological disorders greatly increases.
- Alcohol consumption of 3 or more glasses of alcohol/week.

Exclusion criteria

- Presence of a neurological and psychiatric disorder (for example, Alzheimer's Disease, Parkinson's Disease, sleep disorders, etc.)
- Medication use (with the exception of the contraceptive pill and paracetamol)
- Drug use
- Excessive alcohol consumption (defined as> 21 units of alcohol/week)
- Smoking on average > 10 cigarettes / day
- Female participants may not be pregnant (this is checked by means of a pregnancy test) or bebreastfeeding.
- In possession of an initial drivers license.

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):	08-01-2016
Enrollment:	99
Type:	Actual

Ethics review

Approved WMO

Date:	17-12-2015
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
CCMO	NL54400.068.15