Establish limits for fitness to drive with prolonged use of ICADTS class III medication

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

Summary

ID

NL-OMON41276

Source
ToetsingOnline

Brief title
ICADTS III

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
depression; anxiety; sleeping problems

Health condition

depressieve stemmingsstoornissen - en afwijkingen; slaapstoornissen - en afwijkingen

Research involving
Human

Sponsors and support

Primary sponsor: Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieu (VROM)
Source(s) of monetary or material Support: Ministerie van Infrastructuur en Milieu

Intervention

Keyword: fitness to drive, ICADTS III, limits, medication

Outcome measures

Primary outcome

The primary outcome measure in this study is the Standard Deviation of Lateral

Position (SDLP; in cm)

Secondary outcome

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

tests:

- Trailmaking A and B

- Digit Symbol Substitution Test

- Adaptive Tachistoscopic Traffic Perception Test

- Reaction Time

- Determination Test

- Vienna Risk-Taking Test Traffic

- Psychomotor Vigilance Task

- Driving simulator tests (Swingdrive; Intersections; Merging; Vigilance-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 the International Council on Alcohol, Drugs and Traffic Safety (ICADTS). Medications are categorized in class I (safe to drive) , class II (be careful when driving) and class III (do not driving).
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 which then is fully mobile, and because he is better employable on the job market.
The proposed study provides general standards and limits concerning use of chronic medications and fitness to drive, and can thus form the basis for science-based regulation of antidepressants, sleeping pills and tranquilizers.

Study objective

The aim is to determine on the basis of the results of this study whether there is measurable effect on the ability to drive after long term use of ICADTS class III drugs. To achieve this goal drugs will be tested out of the groups most commonly used, namely hypnotics (sleeping pills), anxiolytics and antidepressants in therapeutic doses. The neuropsychological assessment of fitness to drive focuses on the following cognitive domains: attention and processing speed, reaction time/ psychomotor functions, sensory - perceptual function, executive function and alertness/vigilance.

Study design

In each of the three medication groups (hypnotics, anxiolytics and anti-depressants) 40 subjects will be included (= 120 patients in total + an expected maximum of 5% dropouts who will be replaced). In each medication group the 40 patients will be matched with 40 healthy control subjects (= 120 cotrol subjects in total + an expected maximum of 5% dropouts who will be replaced). Matching will be done on: age, gender en driving experience. Furthermore, an additional group of 20 patients will be enrolled, they all have to use 2 or more ICADTS category III medicines (= Multi User Group). Condition is that also in this extra group all used ICADTS Category III drugs have to be part of the 3 studied medicine groups. The matching of the 20 patients participating in the multi-user group will take place by attempting to link them to a control subject, which has already been linked to a patient in one of the drug groups. If there is no good match available in this group, a new control subject will be sought and tested.
In each medication group 2 periods of medication consumption will be distinguished namely longer than 6 months but shorter than 3 years and more

than 3 years (at steady dosages). Every effort shall be made to achieve an equal division of the patients between the 2 consumption groups.
When necessary a division of at least 15 and a maximum of 25 is permitted. In the group of 20 patients taking more than one drug from the ICADTS category III this distinction will not be made.

Intervention

In this study chronic users of ICADTS class III medication will be included. The drugs tested will be those from the most common used medication groups, namely hypnotiscs, anxiolytics and anti-depressants in therapeutic doses.

Study burden and risks

Prior to participation patients and control subjects who are interested in participating in the study fill in a medical questionnaire. This is presented to the Medical Supervisor and he assess whether the person is eligible to participate in the study. Each volunteer comes to the test center twice. The first time is for a training session. During this visit a short screening (height, weight , vision) will be executed, the volunteer fills in some questionnaires and the cognitive tests are all explained and practiced. Thereafter, the test day takes place. Both visits will last approximately 5 hours.
In this study, chronic users of ICADTS class III drugs are included. We therefore expect no side effects of these drugs during their participation. While driving in the simulator, it is possible that subjects experience simulator sickness (similar to motion sickness). This is explained in advance and they will be closely monitored while driving. It is made clear that they can stop the investigation at any time.

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

Patients: chronic use of ICADTS class III medication (> 6 months)
- age between 21 and 75 (inclusive)
- BMI between 19 an 29 m2/kg (inclusive)
- in posession of a valid drivers license for at least 3 years
- driving experience of at least 3000 km/yeat on average
- sufficient vision

Exclusion criteria

- a neurological disorder
- use of drugs
- excessive alcohol consumption (> 21 glasses of alcohol/week)
- smoking (> 10 cigarettes/day)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2014
Enrollment:	272
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	bromazepam
Generic name:	bromazepam
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	chloordiazepoxide
Generic name:	chloordiazepoxide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Lendormin
Generic name:	brotizolam
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tryptizol
Generic name:	amitriptyline
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Xanax
Generic name:	alprazolam
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-01-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-05-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-08-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-09-2015
Application type:	Amendment
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	EUCTR2013-004936-31-NL
CCMO	NL47435.068.13

Register	ID
Other	Nog niet beschikbaar