# 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

**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

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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 tranguilizers.

#### **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**

#### **Public**

Ministerie van Volkshuisvesting, Ruimtelijke Ordening en Milieu (VROM)

Plesmanweg 1-6 Den Haag 2597 JG NI

#### **Scientific**

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Plesmanweg 1-6 Den Haag 2597 JG NL

## **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