

Validation of driving-related psychometric tests to predict performance on a standard on-the-road test after prolonged wakefulness.

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The aim of the study is to determine which computer tests can be used best to measure changes in driving ability.

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

Summary

ID

NL-OMON37179

Source

ToetsingOnline

Brief title

Predicting impaired driving

Condition

- Other condition

Synonym

n.v.t.

Health condition

n.v.t. Het betreft gezonde vrijwilligers die alleen langer wakker gehouden zullen worden

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: driving ability, prolonged wakefulness, psychometric tests, validation

Outcome measures

Primary outcome

The primary study parameters are:

- the reaction time on the Psychomotor Vigilance Test
- the Standard Deviation of Lateral Position (SDLP) on the standard Highway

Driving Test.

Secondary outcome

De secondary study parameters are accuracy and speed on the other computer tests that will be performed by the subjects. Like:

- Critical Tracking Test
- Divided Attention Test
- Concept Shifting Test
- Useful Field Of View
- Digit Symbol Substitution Test
- Attentional Networks Test
- Determination Test
- Reaction Time Test

Study description

Background summary

This study is part of a series of investigations in which we intend to develop and validate a standardized behavioral test battery. The purpose is to implement this test battery in future clinical drug studies assessing drug effects on cognition and car driving skills. There is still no consensus on the specific tests to be used for such studies, as the correlation between psychometric tests and actual driving impairment has shown to be only low to moderate. We hypothesize that several laboratory tests might be good predictors of actual driving performance.

Study objective

The aim of the study is to determine which computer tests can be used best to measure changes in driving ability.

Study design

The study will be conducted according to a randomized, 2-way cross-over design.

Intervention

The intervention is prolonged wakefulness (24 hrs.)

Study burden and risks

Volunteers' health will be ensured for by letting the subjects fill out a extensive medical questionnaire, that will be evaluated by the research physician.

According to us there are no risks involved in participating in the study.

The burden for the subjects will consist of:

- the rules of life which they must adhere to before and on test days
- the time they spend participating in the study (in total approximately 27 hours)

At the end of each test day the subjects will be transported home by taxi

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

Healthy

Age between 23 and 45 (inclusive)

BMI between 19 and 29 (inclusive)

In possession of a valid driving license for at least 4 years

Driving experience of at least 5000 km/year on average

Normal sleeping pattern

Exclusion criteria

Abnormal sleeping pattern (sleeping disorder; extreme morning or evening type; night shifts)

Smoking

Excessive alcohol use (more than 21 glasses of alcohol per week)

Excessive caffeine use (more than 5 cups of coffee per day)

Use of drugs

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2013
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO	
Date:	11-12-2012
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

CCMO

Other

ID

NL42668.068.12

Nog niet beschikbaar