CALIBRATION AND VALIDATION OF THE STISIM DRIVING SIMULATOR: SIMULATED DRIVING PERFORMANCE UNDER THE INFLUENCE OF ALCOHOL (0.05%, 0.08% AND 0.11%), AND PLACEBO

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

Summary

ID

NL-OMON31608

Source
ToetsingOnline

Brief title
CALIBRATION OF THE STISIM DRIVING SIMULATOR

Condition

- Other condition

Synonym
driving under influence., In het engels: drinking

Health condition

alcoholgebruik

Research involving
Human

Sponsors and support

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

Intervention

Keyword: alcohol, driving, simulation, STISIM

Outcome measures

Primary outcome

weaving of the car and number of errors/collisions

Secondary outcome

driving quality questionnaires

Study description

Background summary

Driving is an example of complex behavior in which several skills and abilities are required simultaneously. In this study, driving performance will be tested utilizing a STISIM Drive simulator (Systems Technology, Hawthorne, CA).

Study objective

The levels of performance decrement for the three blood alcohol concentrations will serve as a historical control for comparing the effects that will be observed with psychoactive drugs in future trials. This will make the results of these future studies more easily to interpret and will provide health care providers and policy makers who read our scientific work with an easy-to-understand and clinically relevant comparison, since most people are more familiar with the effects of alcohol on human performance when compared to psychotropic drugs.

Study design

single blind, cross-over

Intervention

alcohol (0.05%, 0.08%, and 0.11%) and placebo

Study burden and risks

there is no benefit for participants. There is also no risk: alcohol levels are relatively low and performance is tested in a simulator.

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

- 21-50 years old

- Written informed consent (see appendix B)
- Normal static binocular acuity, corrected or uncorrected
- Normal hearing
- Social Drinker (average of 7 to 21 alcoholic drinks per week and experience with drinking 4-6 drinks per occasion)
- Possession of a driver*s license for at least 3 years
- Be considered as reliable and mentally capable of adhering to the protocol.

Exclusion criteria

- Current drug use (positive urine drug screen on the presence of amphetamines (including MDMA), barbiturates, cannabinoids, benzodiazepines, cocaine, and opiates)
- Positive urine pregnancy screen in women
- Present or past use of psychoactive medication
- Positive alcohol breath test
- Prior enrolment in the same study
- Physical or mental illness
- Excessive alcohol use (>21 alcoholic drinks per week)
- Excessive smoking (more than 10 cigarettes per day)
- Intake of caffeine-containing beverages over 5 glasses per day
- Simulator sickness, as determined during the training session

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-06-2008
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO Date:	20-05-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL21124.041.07