A calibration study for the DASS driving simulator: simulated driving performance and event-related potentials under influence of five dosages of ethanol

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

Summary

ID

NL-OMON30247

Source
ToetsingOnline

Brief title
A calibration study for the DASS driving simulator

Condition

- Other condition

Synonym
drinking, driving under influence

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, Calibration, DASS, ERPs

Outcome measures

Primary outcome

The primary study parameters of the study are the steering error of the

simulated driving task, de amplitudes of the recorded event-related potentials,

and the reaction times of the auditory oddball-task.

Secondary outcome

N.v.t.

Study description

Background summary

In future research the effects of pharmacological manipulations on driving performance and attentional processes during driving (by measuring ERPs) will be investigated in the DASS driving simulator. There is no calibration data available with regard to driving performance in the DASS nor for measuring ERPs simultaneously. Because the effects of alcohol are well known, measuring driving performance and ERPs in the DASS under influence of alcohol could provide a calibration measure. Therefore, we propose to study simulated steering performance and ERPs measured during an oddball paradigm, presented during driving and non-driving, under influence of 5 dosages alcohol (0,0 - 0.02 - 0,05 - 0,08 - 0,1 % BAC).

Study objective

To obtain a calibration measure for driving in the DASS driving simulator and secondly to obtain a calibration measure for measuring ERPs during driving in

the DASS driving simulator. Therefore, simulated driving and attentional processes during driving, indicated by ERPs recorded during an auditory oddball task, will be investigated under influence of alcohol. This way a calibration measure for future research with pharmacological manipulations in the DASS with measurement of ERPs will be obtained. The effects of pharmacological manipulations in future research can be compared with the effects of the different alcohol dosages from this study.

Study design

Participants take part in the study for 2-6 weeks. Each participant will participate 5 days (3,5 hours per day). Participation will include doing a simulated driving task, an auditory oddball paradigm and doing the simulated driving task while an auditory oddball paradigm is presented simultaneously and ERPs are recorded.

Intervention

Intervention will consist of five dosages of alcohol: (0,0 - 0.02 - 0,05 - 0,08 - 0,1 % BAC).

Study burden and risks

The risk for the volunteer is very small. There is no risk involved in performing the computertest (simulated driving test) during which ERPs are measured. The alcohol dosages are relatively low and correspond with the normal use of social drinkers.

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

Social drinker (mean < 21 glasses of alcohol per week), no psychological or physical complaints, possesion of a valid drivers license, normal static binocular acuity, normal hearing

Exclusion criteria

Psychological or physical complaints, use of medication, excessive use of alcohol and/or drugs

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	01-05-2007
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2007
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	NL14191.041.06