Invloed van alcohol op aandacht.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25202

Source
NTR

Health condition

dose effects of alcohol

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University

Intervention

Outcome measures

Primary outcome

Dual task performance using a divided attention task. The task combines psychomotor tracking test with peripheral visual search task. Dependent measures are speed and accuracy of responses in both subtasks

Secondary outcome

A one-hour battery of computerized performance tests assessing alertness, sustained attention, visual orienting, executive attention, attention switching, psychomotor speed, postural balance, working memory.

Study description

Background summary

Use of psychoactive medication is associated with increased risks of motor vehicle accidents. New psychoactive medications should therefore be screened early in development for their potential to impair driving related skills. There is no consensus however on the performance test(s) that can be recommended for such purposes. The purpose of this study is therefore to compare the sensitivity of a number of available tests to drug-induced impairment by comparing the dose-effects of alcohol on performance. Twenty-four healthy male and female volunteers will participate in this 4-way double blind crossover design. Alcohol treatment consists of pure ethanol (mixed orange juice) in gender and weight adjusted doses to reach blood alcohol concentrations of 0.0, 0.2, 0.5 and 0.8 mg/ml. Performance tests will be conducted within two hours after each dose of alcohol.

Study objective

Objective of this study is to assess the sensitivity of performance in a number of widely used tests for measuring driver impairment to the dose-effects of alcohol.

Study design

Acute effects. Performance is assessed within two hours after each dose of alcohol.

Intervention

Single oral doses of ethanol mixed with orange juice sufficient to raise Blood Alcohol Concentrations to approximately 0.2, 0.5 and 0.8 mg/ml, and placebo (orange juice only).

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy males and females;

2. Aged between 18 and 30 yrs;

3. BMI between 19 and 29 m2/kg;

4. Social drinkers.

Exclusion criteria

1. History or mental illness;

2. Current physical illness;

3. Use of medication or drugs;

4. Drinking less than 3 glasses alcohol per week or more than 21 glasses of alcohol per week;

5. Execessive use of caffeine or nicotine.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2012
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-02-2012
Application type:	First submission

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
NTR-new	NL3153
NTR-old	NTR3297
Other	METC : 12-3-001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A