The effects of alcohol on brain connectivity pathways and behavioural inhibition: A transcranial magnetic stimulation study

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

Summary

ID

NL-OMON31521

Source
ToetsingOnline

Brief title
Alcohol and transcranial magnetic stimulation

Condition

- Other condition
- Cognitive and attention disorders and disturbances

Synonym
alcohol abuse, alcoholims

Health condition

alcoholisme

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: NWO VENI 451-04-070

Intervention

Keyword: Alcohol, Behavioural inhibition, Brain communication, Transcranial magnetic stimulation

Outcome measures

Primary outcome

(1) Brain communication: (a) between the cerebral hemispheres; (b) between the

cerebellum and the cerebral cortex;

(2) Ability to suppress behavioral responses (inhibition).

Secondary outcome

n.a.

Study description

Background summary

The observation that alcohol use causes reductions in behavioral inhibition is well established. The brain mechanisms underlying these alcohol related changes are however incompletely understood. It has been speculated that the communication between certain brain regions plays an important role. Problematically however, the evidence is indirect and correlational of nature. Paired-pulse transcranial magnetic stimulation (pp-TMS) is an unique method that is able to assess human brain communication directly and in a noninvasive way. Pp-TMS is therefore a unique approach to map the biological effects of alcohol on brain communication.

Study objective

The aim of the present study is get more insight into the effects of alcohol on

acute changes in brain communication en behavioral inhibition. It is hypothesized that alcohol will result cause impairments in the ability to inhibit behavioral responses and that this impairment can be explained by reductions in brain communication.

Study design

Experimental design: Double-blind, placebo controlled, within-subjects
The amount of alcohol that will be administered in order to achieve a blood alcohol concentration of 0.5 promille at the time of testing will be based on the subject's weight. Order of alcohol or placebo administration during the testing sessions will be randomized and counterbalanced.
The experiment will consist of three session of one hour each: Session 1: Intake-Providing procedural information and obtain informed consent; questionnaires; motor trheshold estimations. Session 2: Testing day 1- Breath test; Alcohol or placebo administration / Breath test / pp-TMS to assess communication between the cerebral hemispheres and between the cerebellum and cerebral cortex / Behavioral inhibition task/ Breath test. Session 3: Testing day 2- identical to testing day 1 except for administration

Intervention

On two seperate occassions, participants will consume either an alcoholic (0.5 promille) or a non-alcoholic beverage (0 promille). During both testing sessions transcrnial magnetic stimulation (TMS) will be applied to examine the functional connectivity between different parts of the brain.

Study burden and risks

The main concern when using TMS is its potential to induce a seizure. Safety guidelines, including the limits of stimulation intensity, monitoring of subjects, medical management of induced seizures and contraindications to rTMS as described by the International Federation of Clinical Neurophysiology will be followed strictly, to minimize seizure risk. Other potential adverse effects of rTMS include induction of a muscle tension headache. These are generally mild discomforts that respond promptly to common analgesics. It should furthermore be noted that volunteers can withdraw from the study at any given time.

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

male and female, age: 18-35 years, weight: 50-85kg, non smoking, right-handed

Exclusion criteria

alcohol dependence, history of psychiatric or neurological conditions, drug use, epilepsy, metal in cranium

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2008
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	24-04-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-10-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-09-2008
Application type:	Amendment
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	NL16489.041.07