Magnitude of contextual startle potentiation as a function of inter startle interval: A pilot study and a cross-over alcohol design

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The current protocol aims to test the effects of intervals between subsequent startle measurements on the sensitivity of FPS to alcohol.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON35832

Source
ToetsingOnline

Brief title
Contextual startle potentiation and inter startle interval

Condition

- Anxiety disorders and symptoms

Synonym
Anxiety disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Alcohol, Fear potentiated startle, Method adaptation

Outcome measures

Primary outcome

The magnitude of fear-potentiated startle (FPS).

Secondary outcome

Subjective measures of anxiety (questionnaires).

Study description

Background summary

Human experimental models based on Fear-Potentiated Startle (FPS) are extremely sensitive to manipulations of fear and anxiety an for individual differences in trait anxiety. These models have also been studied extensively for their sensitivity to anxiolytic properties of drugs. There have been some conflicting findings with benzodiazepines, and the aim of this study is to vary a parameter that may affect the sensitivity of the FPS model to the anxiety-reducing properties of GABA-ergic substances.

In previous studies the effect of GABAergic compounds have been observed when the intervals between subsequent startle measurements were long (on average > 20 s; Curtin et al., 1998, 2001; Graham et al., 2005; Grillon et al., 2006; Moberg et al., 2009; Riba et al., 2001), but not when they were short (on average < 20 s; Baas et al., 2002, 2009). Alcohol has comparable effects on FPS as benzodiazepines (Moberg et al., 2009). The current protocol aims to test the effects of intervals between subsequent startle measurements on the sensitivity of FPS to alcohol.
For this purpose, one dosage of alcohol (based on Moberg et al.: 0.08% BAC) is compared to placebo.

Study objective

The current protocol aims to test the effects of intervals between subsequent startle measurements on the sensitivity of FPS to alcohol.

Study design

In the pilot study the version of the FPS model with short and long intervals are compared directly against each other in a cross-over design. In the alcohol study, the short versus long versions are both tested once with a dose of alcohol and once with placebo are tested in 4 test days.

Intervention

Anxiety is induced by means of threat of shock. This is repeated in the alcohol study with a dose of alcohol compared to placebo.

Study burden and risks

The burden on the subjects is during maximally 6 weeks 4 times a testday of 1-1.5 hours. The anxiety induction and the physiological measurements involved has been done by hundreds of participants without serious consequences. The dose of alcohol given during the alcohol study is a little but not much higher than what the group of social drinkers among which we recruit our participants is used to in their daily life.

Because the development of good models for testing anxiolytic drugs is important, we assess that these goals outweigh the relatively small burden and relatively minor risks.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* He/she is aged between 21-50 (in the pilot study, since there is no alcohol administration involved, a minimum age of 18 is sufficient)
* Written informed consent (see appendix E2)
* Normal static binocular acuity, corrected or uncorrected
* Normal hearing
* BMI within the normal range (19-30) (alcohol study only)
* For women, adequate birth control medication is required (alcohol study only)
* Social Drinker (average of 7 to 21 alcoholic drinks per week) and recent experience with the dose of alcohol to be administered (dose is dependent on the weight and gender of the participant) (alcohol study only)
* Be considered as reliable and mentally capable of adhering to the protocol

Exclusion criteria

* Regular drug use in the past month prior to the first test session (during participation no drug use is allowed)
* Pregnancy (alcohol study only)
* Use of psychoactive medication (alcohol study: or medication that cannot be combined with alcohol use) from the last month prior to the first test session or during participation
* Physical or mental illness
* Excessive alcohol use (>21 alcoholic drinks per week) or a score indicating problematic alcohol use on the Alcohol Use Disorders Identification Task (AUDIT)* Excessive smoking (more than 10 cigarettes per day)
* Intake of caffeine-containing beverages over 5 glasses per day
* Small startle responses (a mean of less than 5 µV over nine startle responses) or no startle response on at least one trial of the baseline startle reactivity screening

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2011
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2011
Application type:	First submission
Review commission:	METC NedMec

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	NL36112.041.11