Fear-Potentiated Startle Method Adaptation Studies: Processing of repeatedly presented stimuli

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Testing the feasibility of testing FPS as part of an anxiety test battery several times on one test day (pilot study 1) and repeating this procedure across several test days (pilot study 2).

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

Summary

ID

NL-OMON30886

Source
ToetsingOnline

Brief title
Fear-Potentiated Startle Method Adaptation Studies

Condition

- Anxiety disorders and symptoms

Synonym
induced anxiety in healthy volunteers

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Centre for Human Drug Research,Hoffmann-La Roche,Samenwerking met het onderzoeksinstituut CHDR (Center for Human Drug Research) in Leiden en de firma Hoffmann-La Roche in Basel

Intervention

Keyword: Anxiety, Fear potentiated startle

Outcome measures

Primary outcome

The main study parameter is potentiation of the startle reflex during a condition in which electrical stimuli may be administered in comparison to startle during a safe condition in which electrical stimuli will never be presented (FPS).

Secondary outcome

Skin conductance responses, subjective anxiety.

Study description

Background summary

Fear-Potentiated Startle (FPS) has been recognized as a powerful tool to assess fear and anxiety in animal and human laboratory models. Human models so far have developed procedures to allow multiple FPS test days for purpose of cross-over pharmacological studies. However, for the purpose of screening novel compounds of which the pharmacokinetics is still largely unknown, the method could be improved by assessing FPS several times across one test day. This protocol describes two relatively small pilot studies that test the feasibility of testing FPS several times on one test day (pilot study 1) and repeating this procedure across several test days (pilot study 2). In addition, several other tests will be included to comprise an anxiety test battery that probes several other aspects of anxiety.

Study objective

Testing the feasibility of testing FPS as part of an anxiety test battery several times on one test day (pilot study 1) and repeating this procedure across several test days (pilot study 2).

Study design

This protocol concerns two experimental studies in which FPS is tested several times a day, and across several test days. The FPS test will be embedded in an anxiety test battery that includes questionnaires measuring subjective levels of anxiety and mental stress tests.

Intervention

All subjects undergo a Fear-Potentiated Startle test in which anxiety is induced by means of threat of electrical stimuli administered to the wrist, and evoking startle reflexes as a read-out measure. The FPS test is part of an experimental psychology test battery.

Study burden and risks

The burden involves being present at the institute for a short screening visit and during one test day (pilot study 1) or four test days (pilot study 2), filling out several questionnaires, undergoing several repetitions of the FPS and anxiety test battery, and waiting in between. Mild discomfort may be experienced as a result of the stress inducing components in the test battery. Waiting periods between the repetitions of the anxiety test battery is spent in the waiting room where subjects can read or study for themselves. There is minimal risk involved in participating in this study, apart from maybe developing a mild rash in case the subject is hypersensitive to the electrode material or the conductive paste.

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

- Subject is a legally competent adult, aged 18 to 40.
- Subject is familiar with the procedures of the study, and agrees to participate in the study program by giving written informed consent.

Exclusion criteria

- Subject is mentally or legally incapacitated, has significant emotional problems at the time of the study, or has a history of any significant psychiatric disorder(s). Subjects with extreme psychological responses in the personality questionnaires can be excluded.
- Subject has a history of any cardiac disorder or neurological disease.
- Subject has participated in another FPS trial prior to the start of the study.
- Subject is currently a regular user (including *recreational uses*) of any illicit drugs, or has (a history of) drug or alcohol abuse.
- Subject is unable to discern basic colours red, green and blue.
- Reduced startle reactivity, defined as no discernable response in at least 3 out of the 12 startle stimuli.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2007
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2007
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	NL18570.041.07