

The Effects of Stress on Infralow Brain Activity

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Primary objective: - To measure infralow EEG changes during stress response in healthy subjects. Secondary objective(s): - To investigate if cortisol levels relate to ISA. - To explore ISA activity as a potential biomarker for stress. - To formulate...

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

Summary

ID

NL-OMON46371

Source

ToetsingOnline

Brief title

Infralow Activity in Stress.

Condition

- Other condition

Synonym

Agitation, Tension

Health condition

Stress

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Apparatuur en medewerkers zijn standaard al aanwezig op het ziekenhuis. Voor verdere informatie zie formulier B.

Intervention

Keyword: Electroencephalography, Infralow activity, Stress

Outcome measures

Primary outcome

The primary outcome measure will consist of changes in infralow EEG activity after stress in comparison with a control at rest.

Secondary outcome

Secondary outcomes consist of relating ISA to cortisol levels, and differences between responses to stress induced by the ice-water test and stress induced by physical exercise.

Study description

Background summary

Stress affects brain function in various ways. It is also associated with an increased likelihood of seizures in patients with epilepsy. The pathophysiology of this relationship is not well understood. A candidate mechanism is infralow brain activity. Very slow brain oscillations with frequencies below 0.1Hz have been reported to be increased during stress and recently we and others have shown that this infralow activity (ISA) is associated with fluctuations in cortical excitability. We further hypothesize that ISA is influenced by the stress hormone cortisol.

Here, we will study the relationship between ISA and stress by exposing healthy volunteers to two different stressors: the ice water test and strenuous physical exercise. If this relationship between stress and ISA is indeed shown in this study, this may explain the decreased seizure threshold in patients with stress-related seizures and also offers potential as a novel biomarker for

stress related cerebral pathology.

Study objective

Primary objective:

- To measure infraslow EEG changes during stress response in healthy subjects.

Secondary objective(s):

- To investigate if cortisol levels relate to ISA.
- To explore ISA activity as a potential biomarker for stress.
- To formulate hypotheses about the generators of ISA.

Study design

This is a randomised crossover pilot that will run for 20 weeks.

Intervention

- Ice-water test
- Physical exercise test

Study burden and risks

Each subject will undergo two EEG measurements, during which he will experience stress. In the first measurement, stress will be induced by submerging a hand in ice-cold water. In the second measurement, the subject will perform strenuous physical exercise.

EEG is a routine, everyday investigation. Serious or major adverse events are not expected and the risk of an increase of morbidity or mortality is negligible. Potential detrimental effects are discomfort and local skin defects caused by the EEG electrodes. In case of important skin defects, or distress, electrodes will be removed.

A physical exercise test is generally safe, and complications are rare. But, as with any medical procedure, there is a risk of complications, including low blood pressure, arrhythmias and an exceedingly small chance of myocardial infarction. However, these complications are comparable to regular strenuous exercise such as ascending a staircase or jogging.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Above 18 years of age.

Exclusion criteria

Neurological disorder (e.g. epilepsy).

Pathology that influences EEG registration.

Cardiac or respiratory diseases resulting in limited exercise tolerance.

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO	
Date:	06-02-2018
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21197
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64173.044.17
OMON	NL-OMON21197