Modulation of Electrical Brain Responses by Nociceptive Stimulus Properties and Stimulus Detection: an Exploratory Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44357

Source
ToetsingOnline

Brief title
Modulation of Electrical Brain Responses by Nociceptive Stimulus Properties

Condition

- Other condition

Synonym
pain

Health condition

(chronische) pijn, perifere sensitisatie, centrale sensitisatie

Research involving
Human

Sponsors and support

Primary sponsor: MIRA Institute for Biomedical Technology and Technical Medicine, University of Twente
Source(s) of monetary or material Support: NWO: TTW

Intervention

Keyword: chronic pain, electrocutaneous stimulation, evoked potential, nociception

Outcome measures

Primary outcome

Several types of nociceptive stimuli will be applied, while the subject*s response (detected or not detected) and the stimulus related EEG epochs will be measured. This data will be used for computation of a linear mixed-model describing the influence of stimulus parameters on the nociceptive evoked potential.

Secondary outcome

Analysis to determine if and how the EEG signal is dependent on stimulus properties like the inter-pulse interval, stimulus amplitude and stimulus detection.

Study description

Background summary

The development of treatments for chronic pain requires a more profound understanding of the physiological and psychological aspects of chronic pain. Several types of chronic pain are linked to increased sensitivity of the central nervous system [1]. Therefore, it is important to study the underlying mechanisms of this increased sensitivity. However, one major obstacle is the lack of an objective measure of peripheral and central sensitivity. Tracking psychophysical thresholds of nociceptive specific electrocutaneous stimuli can facilitate the investigation of the underlying mechanisms of sensitization [2].

Recently, a subjective method was developed for tracking multiple psychophysical thresholds over time, referred to as multiple threshold tracking (MTT), which has been shown sensitive to central changes in nociception [3]. An objective measure of nociception related activity in the central nervous system is the electroencephalographic (EEG) signal. Multiple-trial averages of this signal, referred to as evoked potentials (EPs), have been shown to reflect nociceptive sensitivity to changes in stimulus parameters such as the number of pulses [4, 5] or number of trials [6]. Since MTT has been shown to be effective in measuring the effect of stimulus parameters on stimulus detection, while the EP has been shown to reflect neurophysiological activity related to stimulus processing, a combination of both techniques might provide insight into the relation between neurophysiological activity and nociceptive stimuli. Both measures are subject to a large amount of noise as well as variation between measurements, leading to a poor signal-to-noise ratio (SNR). Doll et al. [3] have shown that a generalized linear mixed model (GLMM) can be used to account for this variation in MTT measurements, while computing an estimate of the within-subject psychophysical function that is robust to noise. A similar mixed-regression analysis of the EPs during MTT is expected to successfully account for between-subject variations, and provide objective measures of peripheral and central sensitization.

Study objective

The primary objective of this study is to describe the quality and content of electrical brain responses of pain free subjects to electrocutaneous stimuli during multiple threshold tracking, by determining the signal-to-noise ratio of averaged responses and by exploration of the use of generalized linear mixed models to explain the variability in these responses.

Study design

Mono-center, cross-sectional study.

Study burden and risks

The participants will be asked to come to the Human Physiology Lab of the BSS Group at the University of Twente for one session. First, the participant is familiarized with the stimuli by stepwise application of increasing stimuli until stimulus detection. During the experiment, the participant will receive randomized stimuli around the detection threshold according to the multiple threshold tracking paradigm. All participants will be compensated for their participation. The participants will obtain no direct personal benefit.

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

Age between 18 and 40 years old.

Exclusion criteria

* Participant refusal during the study.
* Language problems.
* Skin problems at site of stimulation or EEG recording.
* Diabetes.
* Implanted stimulation device.
* Pregnancy.
* Usage of analgesics within 24 hours before the experiment.

* Consumption of alcohol or drugs within 24 hours before the experiment.
* Pain complaints at the time of the experiment.
* A medical history of chronic pain.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	10-11-2017
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

No registrations found.

In other registers

Register	ID
CCMO	NL62721.044.17