Exploration of the effects of HFS-induced secondary hyperalgesia on the NDT-EP method

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25830

Source
NTR

Brief title
NDT-EP + HFS

Health condition

None

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: Dutch Research Council (NWO) through the NeuroCIMT research program (P14-12, project 2)

Intervention

Outcome measures

Primary outcome

(1) Nociceptive Detection Thresholds (NDTs)
(2) EEG signals

(3) Numerical Rating Scale to mechanical punctate stimulation

Secondary outcome

(1) Participant characteristics (Age, sex, handedness)
(2) Response time to stimuli
(3) Electrode-skin impedance

Study description

Background summary

Chronic pain often is results from disturbed processes in the central nervous system. Once chronic pain is established, treatment is relatively ineffective, with – at best – one patient in three or four achieving 50% pain intensity reduction. Early detection and therapeutic action would mean better treatment outcome and less clinical efforts per patient, but appropriate diagnostic tools are lacking. An increased sensitivity to noxious stimuli is widely recognized as a key factor in chronic pain development. Noxious stimuli are processed by neural mechanisms at several stages in the ascending pathway from periphery to brain, into a conscious pain experience. As a response to injury or disease, maladaptive changes in this pathway may result in an increased pain sensitivity. Clinical observation of the specific malfunctioning of peripheral and central components of this pathway is limited at present, but would permit a better understanding and early selection of interventions for treatment or prevention of chronic pain. Recently, we developed a new method for observing the properties of nociceptive processing utilizing subjective detection of electrocutaneous stimuli in combination with objective neurophysiological brain responses (NDT-EP). In this method, nociceptive afferents are activated by temporally defined current stimuli with varying number of pulses and varying inter pulse intervals. As these different temporal stimulus properties result in different excitation of nociceptive processing mechanisms of the ascending system, subsequent processing of stimulus-response pairs (SRPs) into estimated nociceptive detection thresholds (NDTs) and Evoked brain Potentials (EPs) of multiple stimulus types may provide information about the properties of these mechanisms.

A crucial step in exploring whether the above method could serve as a diagnostic tool is the assessment of the observability of changes in nociceptive function which are relevant for the development or maintenance of chronic pain. This can be achieved by measuring the effect of a well characterized and demonstrated alteration in nociceptive processing mechanisms on the NDTs and EPs. Other research groups have demonstrated that high frequency electrocutaneous stimulation (HFS) of sufficient duration and intensity can be used for prolonged activation of central sensitization mechanisms. These central sensitization effects are observed as a post-HFS secondary hyperalgesia to pin-prick stimuli and considered to play a key role in the development of chronic pain. Other results show that HFS also modulates the EPs obtained by electrocutaneous stimulation on the site of induced secondary hyperalgesia. Recently during a pilot study here at the University of Twente, we have

assessed that HFS is technically feasible to implement in our lab.

Study objective

The research is of of exploratory nature and therefore does not have hypotheses

Study design

Only one visit at a single time point is required.

Intervention

High Frequency Stimulation

Contacts

Public
University of Twente
Niels Jansen

+31 6 28 37 19 52
Scientific
University of Twente
Niels Jansen

+31 6 28 37 19 52

Eligibility criteria

Inclusion criteria

(1) A signed, written informed consent; (2) Age between 16 and 40

Exclusion criteria

(1) Participant refusal during the study; (2) Language problems; (3) Skin problems at site of stimulation or EEG recording; (4) Diabetes; (5) Implanted stimulation device; (6) Pregnancy; (7) Usage of analgesics within 24 hours before the experiment; (8) Excessive consumption of alcohol or drugs within 24 hours before the experiment; (9) Pain complaints at the time of the

experiment; (10) (A medical history of) chronic pain

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	14-09-2021
Application type:	First submission

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
NTR-new	NL9737
Other	CMO Regio Arnhem-Nijmegen : 2020-6265

Study results