CutaStim: Test-retest reliability of a superficial stimulation electrode for pain sensitivity measurements

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28814

Source
NTR

Health condition

Chronic pain

Sponsors and support

Primary sponsor: University of Twente, Biomedical Signals and Systems
Source(s) of monetary or material Support: Eerste geldstroom

Intervention

Outcome measures

Primary outcome

Electrical pain threshold (EPT)

Current pain (NRS)

Past pain (NRS average over last 7 days)

Secondary outcome

Central Sensitization symptoms: Central sensitization inventory (CSI) and central sensitization questionnaire (CSQ)
Neuropathic pain symptoms: PainDETECT questionnaire (PD-Q)

Study description

Background summary

Chronic pain is a highly prevalent condition, with approximately 1 in 5 suffering from it in Europe. It has a large impact on the quality of life, but also increases costs of global health care and absenteeism at work. A wide spread increased sensitivity of the central nervous system to noxious stimulation plays a major role in the development and maintenance of chronic pain, and can be observed as a decreased pain threshold for electrocutaneous stimulation. Although many clinical studies have demonstrated decreased electrical pain thresholds (EPTs) in groups of chronic pain patients, the measurement variability is still substantial due to the use of non-optimal stimulation electrodes. The presently used electrodes cause a deep and non-selective activation of both pain and non-pain related nerve fibers, which hampers the patient in determining the pain threshold. Therefore, the CutaStim electrode has been designed with improved selectivity towards pain related nerve fibers in the superficial skin. We hypothesize that the CutaStim electrode has a higher measurement reliability.

Study objective

It is hypothesized that the CutaStim electrode will have a higher one week test-retest reliability than the currently used electrodes.

Study design

EPT and NRS at both visits (W0 and W1); CSI, CSQ and PD-Q only at first visit (W0)

Intervention

None

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Both groups: A signed, written informed consent; Age between 35 and 65.

Pain patients: Enrolled in a pain rehabilitation program.

Exclusion criteria

Both groups: Refusal during the study; Language problems; Skin problems; Unable to undergo eQST measurement; Diabetes; Implanted stimulation device;
Pregnancy

Pain patients: Average pain intensity of last 7 days of <2 on a NRS scale.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2017
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49880
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7415
NTR-old	NTR7648
CCMO	NL60368.044.17
OMON	NL-OMON49880

Study results

Summary results
None