CutaStim: Reliability of a superficial stimulation electrode for pain sensitivity measurements

Published: 08-08-2017
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The primary objective is to compare the one week test-retest reliability of the CutaStim electrode to self-adhesive conventional electrodes for pain sensitivity measurements.

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

Summary

ID

NL-OMON49880

Source
ToetsingOnline

Brief title
CutaStim test-retest reliability

Condition

- Other condition

Synonym
Chronic pain

Health condition

Chronische pijn, centrale sensitisatie

Research involving
Human

Sponsors and support

Primary sponsor: Onderzoeksgroep Biomedical Signals and Systems (BSS), University of Twente
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Pain, Electrocutaneous stimulation, Quantitative Sensory Testing

Outcome measures

Primary outcome

* eQST: Electrical pain threshold (EPT) [mA]

* Current pain: NRS of the current pain intensity.

* Past pain: Average NRS of the past seven days.

* Central Sensitization Symptoms: Central sensitization inventory (CSI) and

central sensitization questionnaire (CSQ)

* Neuropathic Pain symptoms: PainDETECT questionnaire (PD-Q)

Secondary outcome

* Patient characteristics (age, sex, BMI)

* Current medication intake

* ICD-code

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

The primary objective is to compare the one week test-retest reliability of the CutaStim electrode to self-adhesive conventional electrodes for pain sensitivity measurements.

Study design

Mono-center, cross-sectional study.

Study burden and risks

The participants will be asked to come to Roessingh for two session. During the first session (max. 45 minutes), The familiarization starts after signed informed consent has been obtained. During this session, the participant will be randomized and training/practice with the EPT measurement will be performed. The first EPT measurement will start right after the familiarization session. During the second session (max. 20 minutes), which will be scheduled approximately one week after the first session, another EPT measurement will be done. The appointments of all included patients will be scheduled on days where patients are already scheduled for a regular visit. Controls without chronic pain syndrome are asked to visit RRC two times. All participants will be compensated for the spent time. 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

Enrolled in a pain rehabilitation programme at Roessingh (Patients).
A signed, written informed consent. (Healthy controls and patients).
Age between 35 and 65 (Healthy controls and patients).

Exclusion criteria

- Participants refusal during the study (Healthy controls and patients)
- Average pain intensity of last 7 days of <2 (Patients only)
- Language problems (Healthy controls and patients)
- Skin problems (Healthy controls and patients)
- Unable to undergo eQST measurement (Healthy controls and patients)
- Diabetes (Healthy controls and patients)
- Implanted stimulation devices (Healthy controls and patients)
- Pregnancy (Healthy controls and patients)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	08-08-2017
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-03-2019
Application type:	Amendment
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: 28814
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL60368.044.17
OMON	NL-OMON28814