Quantitative Sensory Testing in Failed Back Surgery Syndrome and Complex Regional Pain Syndrome Patients during Dorsal Root Ganglion stimulation

Published: 11-12-2015
Last updated: 19-04-2024

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

Summary

ID

NL-OMON44147

Source
ToetsingOnline

Brief title
FBSS study

Condition

- Peripheral neuropathies

Synonym
Failed Back Surgery Syndrome and Complex Regional Pain Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DRG, FBSS, pain thresholds, QST

Outcome measures

Primary outcome

Quantitative Sensory Testing:

* pQST

o Pressure Pain Detection Threshold (PPDT) (N)

* eQST

o Electrical Pain Detection Threshold (EPDT) [mA]

o Electrical Pain Tolerance Threshold (EPTT) [mA]

* Nociceptive Perception thresholds (NPT)

o Stimulus amplitude [mA]

o Responses to stimuli (perceived / not perceived)

o Stimulation time [s]

Secondary outcome

Pain intensity

* Initial pain intensity (NRS; (total population as mean ± SD) *SCS-OFF*

* Pain intensity (NRS; total population as mean ± SD) *SCS-ON*

* Mean (% ± SD) pain reduction during SCS

* Questionnaires

o Brief Pain Inventory

Subjects characteristics

* Age, sex, BMI, ASA classification, smoking habits

o Pain history (duration, intensity etc)

o Medication (i.e. acetaminophen, NSAID*s, opioids)

o Area of paresthesia

* Neurological examination

Study description

Background summary

Severe leg pain after back surgery (Failed Back Surgery Syndrome) of after nerveinjury due to trauma/surgery (CRPS) which is refractory to conservative treatment can be treated with spinal cord stimulation. Several studies showed SCS (in particular dorsal root ganglion stimulation) is effective to reduce pain in FBSS and CRPS patients. Despite promising clinical results, underlying mechanisms of action of SCS are still largely unknown. Quantitative sensory testing (QST) contain psychophysical methods which are used for systematic documentation of alterations and reorganizations of the nociceptive system. Estimation of nociceptive thresholds (e.g., detection threshold or pain threshold) using various modalities (e.g., electrical or mechanical) allow observation of sensory processing under normal and pathophysiological conditions. This pilot study uses quantitative sensory testing (QST) to objectively quantify the impact of SCS on pain and sensory thresholds over the painful area covered by the SCS-related paresthesia compared to findings of a non-painful area with the same subject (no SCS-related paresthesia) and a healthy control group.

Study objective

The primary objective of this study is to investigate attenuation of pain and sensory thresholds during dorsal root ganglion stimulation using QST. The secondary objectives of this study are to investigate 1) To assess changes in pain intensity (NRS) when SCS is activated (SCS-on) as compared to a *SCS-off* period. 2) To assess the correlation between pain ratings using numeric rating scores (NRS) and pain/sensory thresholds with SCS-off and SCS-on.

Study design

single-center, single-arm, observational pilot study.

Study burden and risks

This is a observational study without experimental intervention. The risks are believed to be minimal (minor skin irritation due to ECG and needle electrodes, which resolves spontaneously). After signing the informed consent form, subjects will have a single test session at the Pain Clinics. The medical centre visit is planned on a day where subjects are already scheduled for a regular visit. Several Quantitative Sensory Testing will be performed, and questionnaires filled in by all subjects. All measurements are non-invasive. The total duration of the study is 60 minutes (healthy control group: 25min). The participating subjects 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

- Patients aged 18-55years
- Patients diagnosed with the Failed Back Surgery Syndrome or Complex Regional Pain Syndrome
- Unilateral leg pain
- A spinal cord stimulator was implanted recently (at least 1 month ago)

Exclusion criteria

- Patient refusal
- Diabetes
- Pre-existing neurological- of psychiatric disease
- Alcohol- of drug abuse
- Difficulties in communication
- Recent therapies that influence QST measurements, i.e. neuroablative procedures within 2 months

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-04-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL54728.100.15