Magneto-encephalography (MEG) to image the brain*s role in the analgesic effects of Spinal Cord Stimulation (SCS), an explorative study

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Image with magneto-encephalography (MEG) the supraspinal effects of conventional and burst SCS settings in patients who already have a spinal cord stimulator, to study the analgesic mechanisms of action of SCS and to improve the treatment of chronic...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON46671

Source
ToetsingOnline

Brief title
MEGSCS

Condition

- Peripheral neuropathies

Synonym
cortical correlates of neuropathic pain, workingsmechanisms of spinal cord stimulation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Canadian Institutes of Health Research: een fellowship van de Canadese overheid om dit onderzoek te doen.

Intervention

Keyword: MEG, pain, spinal cord stimulation

Outcome measures

Primary outcome

Differences in the power in frequency bands in cortical pain processing areas as well as attention areas under the three stimulation settings. Differences in coherence and frequency coupling within pain processing areas, and between pain processing areas and attention areas. Modulation of evoked responses to peripherally applied electrical stimulation.

Secondary outcome

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Study description

Background summary

Spinal Cord Stimulation (SCS) is an invasive last-resort pain treatment and consists of electrical stimulation of the spinal cord dorsal column using an implanted electrode and pulse generator. Despite its efficacy, SCS has limited or no effect in approximately 35% of patients. Attempts to reliably predict treatment success have failed, probably due to our limited understanding of its mechanisms of action.

Study objective

Image with magneto-encephalography (MEG) the supraspinal effects of conventional and burst SCS settings in patients who already have a spinal cord stimulator, to study the analgesic mechanisms of action of SCS and to improve the treatment of chronic pain.

Study design

A explorative prospective placebo controlled imaging study in patients who already have a spinal cord stimulator and matched control subjects with and without chronic pain.

Intervention

In a double-blind randomized design, patients will receive conventional tonic SCS, burst SCS and placebo SCS, each for a one-week period. Four MEG sessions will be performed at baseline and with tonic, placebo and burst SCS. Patients are asked to keep pain-diaries throughout the study period. In addition, 5 age and gender matched control subjects with chronic neuropathic pain (who are preferably on the waiting list for having a SCS implant) will have up to two MEG sessions and 5 age and gender matched control subjects without pain, will have one MEG session to acquire control data.

Study burden and risks

Participating patients already have a stimulator implanted and will evaluate 3x one week with different standard available stimulation settings. They are programmed for one week with placebo stimulation which will probably increase their pain during those weeks. They are also programmed with burst stimulation for one week. According to previous studies, there is a good chance that burst stimulation will cause a further reduction of their pain compared with tonic SCS. There are no health risks associated with the study, nor are there any harmful aspects with respect to participating. If patients benefit from burst stimulation, permanently changing to this mode could be offered at the end of the study. Participating patients should come to the institute to have a MEG scan four times during the study period. There are no risks associated with MEG imaging. Control subjects without pain will have one MEG recording session and control subjects with chronic pain will have up to two MEG recording sessions.

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

a patient with SCS must meet the following criteria:
* Over 18 years,
* SCS for at least 3 months,
* Stable response to conventional (tonic) stimulation,
* Pulse generator suitable for burst stimulation,
* Active tip of the implanted electrode at spinal level Th8 or below,
* Pulse generator implanted in the lower body,
* Capable of participation: travelling to the institute and filling in the questionnaires;a control subject with pain must meet the following criteria:
* Over 18 years,
* Chronic neuropathic pain in the lower body part,
* Preferably on a waiting list for a SCS implant,
* Capable of participation: travelling to the institute and filling in the questionnaires.;a control subject without pain must meet the following criteria:
* Over 18 years,
* No pain or other neurological disease,
* Capable of participation: travelling to the institute and filling in the questionnaires.

Exclusion criteria

* Severe pain that is interfering with the pain that the SCS is used for,
* Hospitalised or another form of serious decline of general health.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-03-2018
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 26558

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63267.091.17
Other	studie wordt aangemeld zodra goedgekeurd
OMON	NL-OMON26558