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

No registrations found.

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

Summary

ID

NL-OMON26558

Source
Nationaal Trial Register

Brief title
TBA

Health condition

neuropathic pain

Sponsors and support

Primary sponsor: Erasmus University Medical Centre
Source(s) of monetary or material Support: CIHR postdoctoral fellowship, Erasmus University Medical Centre, Stichting Neurobionics Foundation

Intervention

Outcome measures

Primary outcome

Differences in the power in frequency bands in cortical pain processing areas as well as attention areas during resting-state MEG, under various stimulation settings and compared with control subjects.

Secondary outcome

Differences in connectivity within cortical pain processing areas, and between pain processing areas and attention areas during resting-state MEG, under various stimulation settings and compared with control subjects.
Modulation of evoked responses to peripherally applied electrical stimulation, under various stimulation settings and compared with control subjects.

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. In this explorative prospective controlled study in patients who already have a spinal cord stimulator and matched control subjects with and without chronic pain, we image with magneto-encephalography (MEG) the supraspinal effects of several SCS settings

Study objective

Pathological neural oscillations identified with MEG source imaging will be normalized when tonic and/or burst SCS causes pain reduction

Study design

Patients with SCS will have MEG sessions with three different stimualtion settings, eacht with one week in between. Control subjects will have one MEG session.

Contacts

Public
Erasmus University Medical Centre
Cecile de Vos

0652676517
Scientific
Erasmus University Medical Centre
Cecile de Vos

0652676517

Eligibility criteria

Inclusion criteria

• Over 18 years,
• SCS for at least 3 months,
• Stable response to 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

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:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-03-2018
Enrollment:	25
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46671
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8345
CCMO	NL63267.091.17
OMON	NL-OMON46671

Study results