

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26558

Bron

Nationaal Trial Register

Verkorte titel

TBA

Aandoening

neuropathic pain

Ondersteuning

Primaire sponsor: Erasmus University Medical Centre

Overige ondersteuning: CIHR postdoctoral fellowship, Erasmus University Medical Centre, Stichting Neurobionics Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 12-03-2018
Aantal proefpersonen: 25
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 30-01-2020
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46671
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten