Onderzoek naar ruggenmergstimulatie voor de behandeling van diabetische neuropathische pijn, een evaluatie studie

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A study to validate the results from two RCTs that SCS is indeed capable of treating otherwise refractory diabetic neuropathic pain. In addition, we will evaluate the effects of burst stimulation settings in this patient group.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29505

Bron
Nationaal Trial Register

Verkorte titel
SCSDNP2

Aandoening

diabetes mellitus,

diabetic neuropathic pain,

spinal cord stimulation,

diabetische neuropathische pijn,

ruggenmergstimulatie

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente,
Enschede, the Netherlands

Overige ondersteuning: Medisch Spectrum Twente,
Enschede, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome measure is the change in neuropathic pain as measured by visual analogue scale (VAS) score after 6 months of SCS.

Toelichting onderzoek

Achtergrond van het onderzoek

Two Randomised Clinical Trials have shown that in many patients refractory painful diabetic neuropathy can be treated effectively with Spinal Cord Stimulation (SCS). It has also been suggested that novel stimulation settings might be even more effective in this patient population than the standard tonic stimulation settings that have been used in the two RCTs. A validation study to confirm the effects of SCS in diabetic neuropathic pain and to evaluate the effects of burststimulation will be relevant.

The study is a prospective, double-blind validation study.

20 patients with refractory diabetic neuropathic pain will be included. They should be eligible for spinal cord stimulation and have VAS scores for pain > 5. All patients will have a trial stimulation period with an external SCS pulse generator. If the trial is successful (> 25% pain reduction) an SCS system will be implanted. - During the first 12 weeks, SCS settings are adjusted and evaluated by the patients. Settings include 3 weeks of tonic, high burst, low burst stimulation settings and SCS off, in random order. Principal investigator and patients will be blind for the stimulation setting. - After completion of the 6 months study treatment period, all patients will be followed in accordance with standard medical care.

Primary outcome measure is the change in neuropathic pain as measured by VAS score after 6 months of SCS.

Doel van het onderzoek

A study to validate the results from two RCTs that SCS is indeed capable of treating otherwise refractory diabetic neuropathic pain. In addition, we will evaluate the effects of burst stimulation settings in this patient group.

Onderzoeksopzet

After baseline and implantation, patients will have study visits after 3,6,9, and 12 weeks and a final study visit at 6 months

Onderzoeksproduct en/of interventie

Implantation of spinal cord stimulator and stuctured evaluation of various stimulation settings (tonic, high amplitude burst, low amplitude burst, placebo)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Peripheral neuropathic pain that exists for more than 6 months and is due to diabetes mellitus.

- Patient cannot be treated further otherwise according to patients’ medical specialist.

- The pain-sensation on a visual analogue scale is 5 or more

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age < 18 years.

- Psychological problems that requires treatment.

- Addiction (i.e. compulsory) to: drugs, alcohol, medication.

- Insufficient cooperation by patient (motivation, insight or communication).

- Coagulation irregularities/ Anti-coagulants.

- Immune compromised.

- Life expectancy less than 1 year.

- Pregnancy.

- Local infection at the site of the incision

- Implanted pacemaker, ICD or other neuromodulation system

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-06-2017

Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-09-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45247
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6515
NTR-old	NTR6704
CCMO	NL60465.044.17
OMON	NL-OMON45247

Resultaten