Spinal cord stimulation for treating diabetic neuropathic pain; a validation study

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To validate the results from two RCTs that SCS is indeed capable of treating otherwise refractory diabetic neuropathic pain, and to evaluate the effects of burst stimulation settings in this patient group.

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

Summary

ID

NL-OMON45247

Source
ToetsingOnline

Brief title
SCSDNP2

Condition

- Peripheral neuropathies

Synonym
chronic pain due to diabetes mellitus, painful diabetic neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Neurochirurgie MST en Menzis

Intervention

Keyword: diabetic neuropathic pain, spinal cord stimulation

Outcome measures

Primary outcome

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

Secondary outcome

Secondary objectives are an evaluation of the efficacy of SCS treatment in patients with diabetic neuropathic pain as measured by change in pain intensity at all visits, and an evaluation of following health outcome measures: McGill Pain Questionnaire, EuroQoL 5D, HADS, PVAQ, changes in pain medication, patient*s satisfaction and stimulation preference.

Study description

Background summary

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. In several countries diabetic neuropathy has now become a reimbursed indication for SCS. A validation study to confirm the effects of SCS in diabetic neuropathic pain will be relevant.

Study objective

To validate the results from two RCTs that SCS is indeed capable of treating otherwise refractory diabetic neuropathic pain, and to evaluate the effects of burst stimulation settings in this patient group.

Study design

The study is an open, prospective, validation study consisting of:
- A pre-study screening period during which patients will be evaluated for study eligibility.
- Trial stimulation and surgical implantation of the SCS system.
- 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.
- Evaluation visits (to acquire pain scores and other health outcome measures) will occur at 3, 6, 9 and 12 weeks, and 6 months after implantation.
- After completion of the 6 months study treatment period, all patients will be followed in accordance with standard medical care.

Intervention

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.

Study burden and risks

Implantation of a spinal cord stimulator is a standard and common procedure in Medische Spectrum Twente. The risks of the procedure are similar to other small surgical procedures,

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

- 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.

Exclusion criteria

- 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

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	spinal cord stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-06-2017
Application type:	First submission
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

ID: 29505
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60465.044.17