An open prospective randomized long-term effectiveness study, comparing best medical practice with or without adjunctive spinal cord stimulation in patients with chronic diabetic neuropathic pain.
(SCS 001)

Gepubliceerd: 14-12-2006 Laatst bijgewerkt: 18-08-2022

To demonstrate superiority over time in treatment of pain of best medical practice with adjunctive SCS Therapy compared to best medical practice without SCS Therapy in patients with chronic diabetic neuropathic pain as measured by VAS score.

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

Samenvatting

ID

NL-OMON25218

Bron
Nationaal Trial Register

Verkorte titel
SCS 001

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

VAS score.
Measured at baseline and 1, 3, 6,
9 and 12 months after inclusion.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Spinal Cord Stimulation (SCS) is an established and safe treatment for patients with certain types of chronic intractable pain. A few uncontrolled trials, including our own study with nine diabetic patients, have shown that patients with
chronic diabetic neuropathic pain might respond well to SCS treatment.
Study goal: What is the long-term clinical benefit of best medical practice with and without adjunctive SCS therapy in patients with chronic diabetic neuropathic pain?
Study Design: The SCS-001 study is an open, prospective, long-term effectiveness study comparing best medical practice with or without adjunctive SCS therapy in patients with chronic diabetic neuropathic
pain. Medisch Spectrum Twente is officially certified to perform this therapy. The treatment contains an intake and baseline period, trial stimulation and possibly surgical implantation of the SCS system and follow-up.
Population: Approximately 45 diabetic patients with chronic neuropathic pain in the lower extremities will be randomized to either the best medical practice with
adjunctive SCS therapy or best medical practice without SCS therapy.
Study Endpoints: The primary objective of the SCS-001 study is to demonstrate superiority over time in treatment of pain of best medical practice with adjunctive SCS therapy compared to best medical
practice without SCS therapy in patients with chronic diabetic neuropathic pain as measured by VAS score.
The most important secondary objectives of the SCS-001 study are the evaluation of the effect of SCS therapy over time and the evaluation of the reported pain (like pain intensity, pain duration, pain pattern),
pain medication, quality of live (SF-36) and safety and tolerability of the SCS system in this patient population
Risk: The risk of best medical practice with or without adjunctive SCS therapy for the treatment of chronic pain is small. SCS therapy is an established treatment and Medisch Spectrum Twente is officially
certified to perform this therapy.

Doel van het onderzoek

To demonstrate superiority over time in treatment of pain of best medical practice with adjunctive SCS Therapy compared to best medical practice without SCS Therapy in patients with chronic diabetic neuropathic pain as measured by VAS score.

Onderzoeksproduct en/of interventie

After a baseline period patients will be randomized to either the best medical practice with adjunctive SCS therapy arm or the best emdical practice without adjunctive SCS therapy arm. The control group will be followed simultanously with the SCS-treatment group.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Chronic, diabetic, peripheral neuropathic pain that exists for more than one year;
2. Patient cannot be treated further otherwise according to patients' medical specialist;
3. The pain-sensation on a VAS-scale is minimal 5 (recording both for day and night time).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years;
2. Psychological problems;
3. Neuropathic pain in upper extremities.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2006
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-12-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL829
NTR-old	NTR842
Ander register	: 001
ISRCTN	ISRCTN03269533

Resultaten

Samenvatting resultaten
N/A