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

Published: 17-01-2007
Last updated: 20-05-2024

What is the long-term clinical benefit of best medical practice with and without adjunctive SCS Therapy in patients with chronic diabetic neuropathic pain?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON38404

Source
ToetsingOnline

Brief title
SCS-001

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Peripheral neuropathies

Synonym
chronic neuropatic pain in patients with diabetes

Research involving

Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: Stichting the Neurobionics Foundation

Intervention

Keyword: chronic pain, diabetes, neuropathy, spinal cord stimulation (SCS)

Outcome measures

Primary outcome

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.

Secondary outcome

To evaluate the efficacy over time 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:

• Response rates (greater than or equal to 50% reduction in pain intensity) at all visits.

• Percent of patients that are pain free (>75% reduction in pain intensity) at all visits.

• Mean and median percent change in pain intensity at all visits.

• Pain free time during day and night.

To compare the effects over time of best medical practice with adjunctive SCS Therapy compared to best medical practice without SCS Therapy on the following health outcome measures:

• McGill Pain Questionnaire

• EuroQoL 5D.

• Changes in pain medication.

• Compliance rates.

To evaluate over time the safety and tolerability of best medical practice with adjunctive SCS Therapy using information on treatment emergent adverse events, device complications, and premature study withdrawal.

Study description

Background summary

Spinal cord stimulation (SCS) is an established treatment for patients with chronic intractable pain. Few studies to date have concentrated on the use of SCS in peripheral neuropathy. Most studies involved sources of peripheral neuropathic pain of mixed etiology, and therefore do not possess adequate descriptions of the effectiveness of SCS for diabetic peripheral neuropathy specifically. Recently, De Vos and co-workers carried out an SCS efficacy study in eleven diabetic patients with chronic pain who did not respond to conventional treatment. Neuropathic pain relief was assessed by visual analogue scale (VAS). However, no direct comparison between SCS and standard use of medication(s) has been made in a prospective, randomized, long-term study.

Study objective

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

Open, Prospective, Randomized, Parallel-group, Comparative, Long-tern Effectiveness Study

Intervention

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

Study burden and risks

The risk associated with participation in the SCS-001 study is low. The components of the spinal cord stimulation system to be used in this study will be those commercially available and described in the protocol of the Dutch Neuromodulation study group.

Contacts

Public
St. Jude Medical

Da Vincilaan 11 - box F1
Zaventem 1935
BE
Scientific
St. Jude Medical

Da Vincilaan 11 - box F1
Zaventem 1935
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

chronic, peripheral diabetic neuropathic pain that exists for more than one year
patient cannot be treated further otherwise according to patient's medical specialist
pain sensation on a VAS scale is minimal 5 (recording both for night and day)

Exclusion criteria

age < 18 years
psychological problems
neuropathic pain in upper extremities

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2007
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	spinal cord stimulation (SCS)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-01-2007
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	16-03-2007
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-03-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL13322.044.06