# 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)

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25218

**Source**
NTR

**Brief title**
SCS 001

### Sponsors and support

**Primary sponsor:** none
**Source(s) of monetary or material Support:** none

### Intervention

### Outcome measures

**Primary outcome**

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

**Secondary outcome**

1. Response rates (greater than or equal to 50% reduction in pain intensity) at all visits;
2. Percent of patients that are pain free (>75% reduction in pain intensity) at all visits;
3. Mean and median percent change in pain intensity at all visits;
4. Pain free time during day and night.
5. McGill Pain Questionnaire;
6. Short Form 36;
7. Changes in pain medication;
8. Compliance rates.
9. Emergent adverse events;
10. Device complications;
11. Premature study withdrawal.

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

# Study description

**Background summary**

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.

### Study objective

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.

### Intervention

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.

## Contacts

**Public**
Medisch Spectrum Twente, Department of Neurosurgery,
P.O. Box 50000
C.C. Vos, de
Enschede 7500 KA
The Netherlands
+31 (0)53 4873532
**Scientific**
Medisch Spectrum Twente, Department of Neurosurgery,
P.O. Box 50000
C.C. Vos, de
Enschede 7500 KA
The Netherlands
+31 (0)53 4873532

## Eligibility criteria

### Inclusion criteria

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).

### Exclusion criteria

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

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Factorial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-08-2006 |
| Enrollment: | 45 |
| Type: | Anticipated |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 14-12-2006 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL829 |
| NTR-old | NTR842 |
| Other | : 001 |
| ISRCTN | ISRCTN03269533 |

# Study results

**Summary results**
N/A