# An open prospective randomised long-term effectiveness study, comparing best medical practice with or without adjunctive Spinal Cord Stimulation in patients with chronic diabetic neuropathic pain

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
22/01/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/01/2007	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
14/01/2021	Nutritional, Metabolic, Endocrine	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

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# Additional identifiers

# Protocol serial number

NL829, NTR842

# Study information

### Scientific Title

An open prospective randomised long-term effectiveness study, comparing best medical practice with or without adjunctive Spinal Cord Stimulation in patients with chronic diabetic neuropathic pain

### Acronym

SCS 001

### **Study objectives**

To demonstrate superiority over time in treatment of pain of best medical practice with adjunctive Spinal Cord Stimulation (SCS) therapy compared to best medical practice without SCS therapy in patients with chronic diabetic neuropathic pain as measured by Visual Analogue Scale (VAS) score.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approval received from the local ethics committee (Medisch Ethische Toetsings Commissie of Medisch Spectrum Twente) on the 17th January 2007 (trial no: P06-34; approval letter: METC /07022.aa; approval letter: RvB/gh/0039-07/73.0).

### Study design

Randomised, controlled, factorial trial

## Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Diabetic neuropathic pain

### Interventions

After a baseline period patients will be randomised to:

- 1. Best medical practice with adjunctive SCS therapy arm, or
- 2. Best medical practice without adjunctive SCS therapy arm.

The control group will be followed simultaneously with the SCS-treatment group.

# **Intervention Type**

Other

### Phase

**Not Specified** 

## Primary outcome(s)

VAS score: measured at baseline and one, three, six, nine and 12 months after inclusion.

### Key secondary outcome(s))

- 1. Response rates (greater than or equal to 50% reduction in pain intensity) at all visits
- 2. Percent of patients that are pain free (more than 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 one, three, six, nine and 12 months after inclusion.

### Completion date

01/08/2008

# Eligibility

### Key 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 five (recording both for day and night time)

### Participant type(s)

**Patient** 

### Healthy volunteers allowed

No

# Age group

Adult

### Sex

**Not Specified** 

### Total final enrolment

11

### Key exclusion criteria

- 1. Aged less than 18 years
- 2. Psychological problems
- 3. Neuropathic pain in upper extremities

### Date of first enrolment

01/08/2006

# Date of final enrolment

01/08/2008

# Locations

### Countries of recruitment

Netherlands

Study participating centre Medisch Spectrum Twente Enschede Netherlands 7500 KA

# Sponsor information

### Organisation

Medisch Spectrum Twente (The Netherlands)

### **ROR**

https://ror.org/033xvax87

# Funder(s)

# Funder type

Hospital/treatment centre

### Funder Name

Medisch Spectrum Twente (The Netherlands)

### **Funder Name**

Stichting TWIN (The Netherlands)

# **Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2009	14/01/2021	Yes	No