

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

22/01/2007

Recruitment status

No longer recruiting

Registration date

22/01/2007

Overall study status

Completed

Last Edited

14/01/2021

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

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).

Primary study design

Interventional

Study design

Randomised, controlled, factorial trial

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