ISRCTN03269533 https://doi.org/10.1186/ISRCTN03269533

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
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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.

Overall study start date
01/08/2006

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

Age group
Adult

Sex

Not Specified

Target number of participants
45

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)

Sponsor details
P.O. Box 50000
Enschede
Netherlands
7500 KA

Sponsor type
Hospital/treatment centre

Website

http://www.ziekenhuis-mst.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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