Effect of Spinal Cord Stimulation in Painful Diabetic Polyneuropathy (PDP study) A pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON32639

Source
ToetsingOnline

Brief title
PDP Study

Condition

- Diabetic complications
- Peripheral neuropathies

Synonym
Pain due to diabetic nerve damage, painful distal symmetrical diabetic polyneuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Neuromodulation, Neuropathic Pain, Painful Diabetic Polyneuropathy, Spinal Cord Stimulation

Outcome measures

Primary outcome

The main study parameter will be the pain intensity as measured on a weighted NRS according to Jensen and a Patient Global Impression of Change for pain measured on a 7-point Likert scale.

Secondary outcome

- The practical feasibility of the test procedures will be monitored during the study. The time needed to perform all quantitative sensory testing procedures will be recorded by the examiner. The patients will be asked to record time filling out the questionnaires.

- During implantation of the SCS electrode, the possibility to induce paresthesias in both lower limbs using 1 stimulation electrode will be assessed. If necessary a second electrode will be implanted.

- Patients will be divided into 2 groups based on the Michigan Diabetic Neuropathy Score (Group 1: no neuropathy-mild neuropathy, Group 2: moderate-severe neuropathy). The correlation between group classification and success of SCS in obtaining pain relief (>50% pain relief measured on a weighed NRS according to Jensen and a PGIC for pain measured on a 7-point Likert scale) will be assessed.

- The correlation between success of SCS in obtaining pain relief (as mentioned above) and the following factors will be assessed: 1) the modified INCAT

sensory sum score and its individual elements, 2) WEST, 3) PPT, 4) CHEPS and 5)

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Study description

Background summary

Diabetic neuropathy is one of the most common complications of Diabetes Melitus (DM). Pain is a frequent symptom of diabetic neuropathy. The prevalence of pain in diabetes patients is estimated between 11-34%. Painful diabetic polyneuropathy (PDP) is a problem with a large societal and economic impact due to the high prevalence of DM and the large impact of PDN on quality of life and daily functioning of patients.
Until ths moment no effective treatment of PDP is available. A large portion of patients experience unacceptable pain despite maximal drug therapy. For this patients spinal cord stimulation (SCS) may be able to provide pain relief.
SCS had been used for over 30 years now for a diversity of neuropathic pain states. Due to this large experience SCS is a safe technique. Percutaneous implantation of the lead is a minimally invasive procedure with a low risk of infection.

Study objective

1) The objective of this study is to confirm the hypothesis that SCS leads to pain relief as indicated by the results of two former pilot studies (Tesfaye et al. 1996 and Vos et al. 2008).
2) The practical feasibility of the test procedures described in the study protocol, including the use of questionnaires by the patients.
3) The technical feasibility of SCS in patients suffering from moderate-to-severe PDP in the lower limbs.
4) The possibility of predicting successful pain relief by SCS by classifying patients according to the Michigan Diabetic Neuropathy Score.
5) Define possible other predictors for successful pain relief by SCS, such as quantitative sensory testing, skin biopsy and glucose regulation.

Study design

The study is a pilot study. A group of 20 patients will receive 2 weeks of trial stimulation. If this results are good, the test lead will be replaced by a definitve lead. The effect will be analysed after 3, 6 and 12 months of treatment. Besides that a number of investigations will be performed to investigate whether factors exist that can predict the effect of SCS.

Intervention

In all patients a test lead will be implanted after inclusion. The lead will be implanted in the operating theatre under local anesthesia using a percutaneous technique with a Tuohy needle. Following this a test stimulation will be performed for 2 weeks. IF this reulst in clinically significant pain relief (50% or more) a definitive lead will be implanted. The pulse generator will be implanted subcutaneously under general anesthesia.

Study burden and risks

The nature of burden and risks consists of 1) implantation of test lead, definitive lead and pulse generator and 2) questionnaire and investigations.

Screening: onderzoek arts afdeling pijnbestrijding en onderzoek arts afdeling neurologie
Tijdsbelasting: 1 uur

Baseline measurement:
- Paindiary measured during 4 days, 3 times per day -> 40 minutes
- Questionnaires ->1 hour
- Quantitative sensory testing -> 2 hours
- Blood withdrawal to determine HbA1c (4 ml) -> 10 minutes
- Skin biopsy -> 10 minutes
Time investment: 4 hours

After 2 weeks trial stimulation:
- Paindiary measured during 4 days, 3 times per day -> 40 minutes
- Questionnaires ->1 hour
- Quantitative sensory testing -> 2 hours
- Blood withdrawal to determine HbA1c (4 ml) -> 10 minutes
Time investment: 3 hours and 50 minutes

3 months measurement:
- Paindiary measured during 4 days, 3 times per day -> 40 minutes
- Questionnaires ->1 hour
Time investment: 1 hour and 40 minutes

6 months measurement:
- Paindiary measured during 4 days, 3 times per day -> 40 minutes
- Questionnaires ->1 hour
- Quantitative sensory testing -> 2 hours
- Blood withdrawal to determine HbA1c (4 ml) -> 10 minutes
Time investment: 3 hours and 50 minutes

12 months measurement:

- Paindiary measured during 4 days, 3 times per day -> 40 minutes
- Questionnaires ->1 hour
- Quantitative sensory testing -> 2 hours
- Blood withdrawal to determine HbA1c (4 ml) -> 10 minutes
- Skin biopsy -> 10 minutes
Time investment: 4 hours

In total, time investment will be maximal 19 hours. This includes filling out questionnaires by the patient and the measurements. Trial stimulation and implantation of the definite lead will will be in total 4 hours. In total time investment will be 23 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Moderate-to-severe PDP in the lower limbs due to diabetes mellitus type 1 or type 2 as diagnosed by clinical symptoms (glove and stocking distribution).
- The pain intended to treat has to be present for more than 12 months.
- Previous treatment has been unsuccessful (insufficient pain relief and/or unacceptable side-effects) with drugs from the following drug categories: 1)Amitriptylin or an other tricyclic antidepressant and/or 2) Pregabalin (Lyrica) or Gabapentin (Neurontin) and/or 3) Duloxetine (Cymbalta) and/or 4) Tramadol or strong opioids
Patients were treated with three drugs fromk the above mentioned drug categories and followed the treatment algorithm for painful diabetic neuropathy according tot Jensen. Starting dosage was based on individual patient characteristics. Each drug was tried for 3 weeks and dosage was raised once if possible. By insufficient pain relief and/or unacceptable side effects, the drug treatment was stopped. Patients reached a steady-state in medication use and it is not allowed to increase dosage during the study.
- Mean pain intensity should be 5 or higher measured on an numeric rating scale (NRS) which will be scored 3 times per day for 4 days
- Patients' age is between 18 and 75 years

Exclusion criteria

- The patient has had neuromodulation therapy during the month before inclusion
- Neuropathic pain most prevalent in the upper limbs (NRS >3)
- Neuropathy or chronic pain of other origin than diabetes mellitus (NRS >3)
- Addiction: drugs, alcohol (5E/day) and/or medication
o Drugs: cocaine, heroine, marihuana.
o Alcohol: wine, beer, liquor.
o Medication: benzodiazepines.
- Insufficient cooperation from the patient (little motivation, understanding or communication)
- Blood clotting disorder
- Immune deficiency (HIV-positive, corticosteroids with a dose equivalent to or higher than prednisolone 10 mg, immunosuppressiva)
- Peripheral vascular disease without palpable peripheral pulses at both feet (inclusion is possible if pulses are absent, but ankle brachial index is between 0.7 and 1.2 in both feet)
- Active foot ulceration
- Life expectancy < 1 year
- Pacemaker
- Local infection or other skin disorders at site of incision
- Psychiatric disorders
- Pregnancy
- Severe cardiac or pulmonary failure (NYHA classification > II)
- Unstable blood glucose control (change in HbA1c > 1,0% (absolute value) in three months prior to inclusion)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2009
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT00802022
CCMO	NL24628.068.08