Spinal Cord Stimulation in Small Fibre Neuropathy: A pilot study

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This study is a pilot study to investigate whether Spinal Cord Stimulation (SCS) combined with best (drug) treatment as usual (TAU) leads to clinically significant pain relief in patients suffering from pain in the lower limbs due to SFN, defined as...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON43640

Source
ToetsingOnline

Brief title
SFN-SCS Study

Condition

- Peripheral neuropathies

Synonym
painfull neuropathy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: neuromodulation, neuropathic pain, small fibre neuropathy, spinal cord stimulation

Outcome measures

Primary outcome

Clinically significant pain relief in patients suffering from pain in the lower

limbs due to SFN, defined as *50% pain reduction on a mean NRS during daytime,

and/or *50% pain reduction on a mean NRS during night-time and/or 2 points

difference (much improved or very much improved) on the Patient Global

Impression of Change (PGIC) for pain and sleep.

Secondary outcome

Secondary objectives are to investigate:

1) The effect of SCS on pain in SFN (pain reduction of *30% on a mean daytime,

night-time, and maximum daily pain (tested separately) using the NRS);

2) The effect of SCS on activity/participation in SFN;

3) The effect on health related quality of life (QoL) in SFN;

4) The effect of SCS on mood in SFN;

5) The effect of SCS on the reduction of pain medication in SFN.

Study description

Background summary

Small fibre neuropathy (SFN) is a disorder in which selectively thinly myelinated and unmyelinated nerve fibres are involved. SFN can cause severe neuropathic pain in combination with autonomic symptoms. So far, the results of symptomatic SFN treatment have been rather disappointing, despite the fact

that new agents have been developed.

Study objective

This study is a pilot study to investigate whether Spinal Cord Stimulation (SCS) combined with best (drug) treatment as usual (TAU) leads to clinically significant pain relief in patients suffering from pain in the lower limbs due to SFN, defined as *50% pain reduction on a mean NRS during daytime, and/or *50% pain reduction on a mean NRS during night-time and/or 2 points difference (much improved or very much improved) on the Patient Global Impression of Change (PGIC) for pain and sleep.

Study design

The study is a prospective pilot study to investigate the effect of SCS on pain in SFN.

Intervention

Patients will receive SCS, with first 2 weeks of trial stimulation and best (drug) treatment as usual.

Study burden and risks

SCS related risks include: lead migration (14%), lead breakage (7%), implanted pulse generator (IPG) migration (1%), loss of therapeutic effect, unpleasant paresthesias (12%), infection or wound breakdown (10%), pain at implanted pulse generator (IPG) incision site (12%), IPG pocket fluid collection (5%).
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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

SFN-diagnosis
age between 18 and 75 years
mean pain intensity 5 or higher on the 11 points numeric rating scale (NRS
pain present for more than 12 months
previous treatment unsuccessful with drugs from the following drugs: tricyclic antidrepressant agent, alpha 2 adrenergic calcium channel agonist/anti-epileptic drug, serotonin-norepinephrine reuptake inhibitor, tramadol or strong opioids
Steady state medication use for at least 2 months

Exclusion criteria

neuromodulation in history
neuropathic pain prevalent in upper limbs exceeding NRS 3
neuropathy or chronic pain of other origin than SFN (NRS >3)
addiction
insufficient cooperation from the patient
bloth clothing disorder
immune deficiency
known peripheral vascular disease
life expextancy < 1 year
pacemaker
local infection or other skin disorders at site of incision
other clinical or unstable, or severe acute or chronic medical or psychiatric/psychological condition or laboratory abnormality that may increase the risk associated with study participation or procedure or may interfere with the interpretation of study results and, in the judgement of the investigator, would make the subject inappropriate for entry into this study
pregnancy

severe cardiac or pulmonary failure
use of opioids

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-05-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	implantaion of spinal cord stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	01-06-2016
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
CCMO	NL53831.068.15