# The CHARACTER SCS Study: A randomised pilot study to assess differenCes in tHe subjects* experience of stimulAtion-Induced paRaesthesiA between two different spinal Cord sTimulation dEvices: the Axium® DoRsal Root Ganglion Stimulation System Versus the Prime Advanced* Dorsal Column Stimulation System

Published: 08-08-2014
Last updated: 21-04-2024

The principal goal of this study is to compare subjects* experience of Spinal Cord Stimulation (SCS) with two different types of SCS device.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON42046

**Source**
ToetsingOnline

**Brief title**
The CHARACTER SCS Study; 12-SMI-2014

### Condition

- Other condition

- Spinal cord and nerve root disorders

**Synonym**
Effect of stimulation on neuropathic (nerve) foot pain

**Health condition**

Neuropathic lower limb pain

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** St. Jude Medical
**Source(s) of monetary or material Support:** Spinal Modulation NV / St. Jude Medical

## Intervention

**Keyword:** Dorsal Root Ganglion, Neuropathic foot pain, Randomised, Stimulation induced paraesthesias

## Outcome measures

**Primary outcome**

The primary objective of this study is to compare subject experiences of SCS

with the two different therapies. We have defined 4 separate assessment tools,

which combined, evaluate the primary endpoint of this study:

• Change in perceived stimulation intensity during normal changes in body

posture (Standing/Sitting and Lying)

• Average number of device activations per day

• Assessment (%) of how much of a subject*s painful area is covered by the

stimulation induced paraesthesia

• Assessment (%) of how much of a subjects non-painful area is also covered by

the stimulation induced paraesthesia

**Secondary outcome**

• Validation of the Paraesthesia Intensity Numerical Rating Scale (PI-NRS)

• Foot / Lower Limb Pain Relief (Visual Analogue Scale)

• Quality of life (EQ-5D-3L)

• Physical functioning (BPI)

• Sleep quality (Bespoke scale created specifically for pain patients treated with neurostimulation, currently being validated in other on going studies)

• Subject satisfaction (7 Point Likert Scale)

• Device safety by monitoring events according to MEDDEV 2.12-1, rev 8

• Pain medication utilisation (Simple notation of current usage through study period)

# Study description

### Background summary

Initial clinical studies have shown that stimulation of the dorsal root ganglion (DRG) can significantly reduce chronic intractable pain. These results have supported the CE marking of the Spinal Modulation neurostimulator system (Axium®) in the management of this pain. Subjects* experience of DRG stimulation therapy, particularly in relation to the precision and stability of the paraesthesia, appears to be different to that experienced with Dorsal Column Stimulation (DCS) therapy. Currently, there is no evidence to suggest that either DCS or DRG stimulation offers superior pain relief to guide a clinician*s choice of device. Clinical practice and field experience suggests that unstable and/or diffuse paraesthesia can be limiting factors in the success of the therapy. To this end, we propose to study the differences of these aspects of the therapy in order to enable better decision making for clinicians involved with these treatments in the future.

### Study objective

The principal goal of this study is to compare subjects* experience of Spinal Cord Stimulation (SCS) with two different types of SCS device.

### Study design

This is a multi-centre, randomized, pilot study in subjects referred with chronic intractable uni/bi-lateral neuropathic lower limb pain (below the knee) with predominant foot pain. Subjects will be randomised to Dorsal Root Ganglion Stimulation (DRG) or Dorsal Column Stimulation (DCS) in a ratio of 1:1 and prospectively followed for 1 year.

### Intervention

Patients will be randomised to one of the two existing treatments.

### Study burden and risks

As both forms of stimulation are accepted forms of neuromodulation in the Netherlands and both are routinely carried out in the participating centres, there are no additional risks to the subjects participating in this study.
There is, as yet, no clinical evidence to suggest that the efficacy of one therapy is superior to the other as a treatment for chronic neuropathic pain.
The collection of follow-up data during routine visits is standard procedure in all neuromodulation Pain Clinics in the Netherlands. We anticipate that the added burden of completing the required Case Report Forms (CRF*s) for this study on the subjects enrolled will equate to an additional 30 minutes per visit. Visits are scheduled in line with routine follow up visits post SCS implant\ so there are no additional visits required for the purpose of the study.
Risk classification based on "kwaliteitsborging mensgebonden onderzoek 2.0" (from the Dutch Federation of University Medical Centers) is classified as "negligible risk".

## Contacts

**Public**
St. Jude Medical

Da Vincilaan 11, F1
Zaventem 1935
BE
**Scientific**
St. Jude Medical

Da Vincilaan 11, F1
Zaventem 1935
BE

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

1) Subject is appropriate for SCS implantation according to standard criteria from the Dutch Neuromodulation Society
2) Subject is 18 to 75 years old
3) Subject is able and willing to comply with the follow-up schedule and protocol
4) Subject has chronic (> 6 months) uni/bi-lateral neuropathic pain in the lower limb(s) (below the knee) with predominant foot pain
5) Minimum baseline pain rating of 50 mm on the VAS in the primary region of pain
6) Subject is able to provide written informed consent

## Exclusion criteria

1) Subject has no other exclusion criteria for SCS implantation according to standard criteria from the Dutch Neuromodulation Society
2) Subject has had corticosteroid therapy at an intended site of stimulation within the past 30 days
3) Subject has had radiofrequency treatment of an intended target DRG within the past 3 months
4) Subject has participated in another clinical study within 30 days
5) Subject has been previously treated with and failed to respond to an implantable neuromodulation therapy

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 14-10-2014 |
| Enrollment: | 40 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Generic name: | The Axium Neurostimulator system / The Prime Advanced Neurostimulator system |
| Registration: | Yes - CE intended use |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 08-08-2014 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 06-01-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# 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 | NCT02250469 |
| CCMO | NL49661.018.14 |