A Post Market Cohort to Assess the Performance of the Spinal Modulation Neurostimulator System for the Management of Chronic Intractable Pain

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The purpose of this Post Market Cohort is to evaluate the commercially available Spinal Modulation Neurostimulator system in the management of intractable chronic pain in patients that are routinely scheduled to receive a Spinal Modulation...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37488

Source
ToetsingOnline

Brief title
Performance of the Spinal Modulation Neurostimulator System

Condition

- Other condition

Synonym
Chronic intractable pain

Health condition

Chronic intractable pain

Research involving

Human

Sponsors and support

Primary sponsor: Spinal Modulation NV
Source(s) of monetary or material Support: Spinal Modulation Inc.

Intervention

Keyword: Chronic-pain, Neurostimulation, Performance, Post Market Cohort

Outcome measures

Primary outcome

1. Pain relief measured using a Visual Analogue Scale (VAS).

2. Device safety by monitoring occurrence of (S)AEs

3. Quality of life (EQ-5D)

4. Physical functioning (BPI, ODI)

5. Oswestry low back pain disability questionairy

6. Pain distribution

7. Paresthesia distribution

8.Subject satisfaction

Secondary outcome

NA

Study description

Background summary

Initial clinical studies have shown that stimulation of the dorsal root ganglion can significantly reduce chronic intractable pain. These results have supported the CE marking of the Spinal Modulation Neurostimulator system in the management of chronic pain. Following the requirements of the AIMDD, Spinal Modulation will also collect clinical data on the commercially available

Neurostimulator Systems.

Study objective

The purpose of this Post Market Cohort is to evaluate the commercially available Spinal Modulation Neurostimulator system in the management of intractable chronic pain in patients that are routinely scheduled to receive a Spinal Modulation Neurostimulator system.

Study design

This is a prospective, multi center, post market cohort to collect data on quality of life, physical functioning, subject safety, and subject satisfaction.

Study burden and risks

There are no additional risks for the patients by participating in this post market cohort. The implantation of the system is a standard procedure in the hospital and the additional data that will be collected consists of questionnaires on pain relief, quality of life and subject satisfaction.

Contacts

Public
Spinal Modulation NV

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Subject is at least 18 years old
2.Subject is able and willing to comply with the follow-up schedule and protocol
3.Chronic, intractable pain in the thoracic, lumbar, and/or sacral distribution(s) for at least 6 months
4.Failed conservative treatments for chronic pain including but not limited to pharmacological therapy, physical therapy and interventional pain procedures for chronic pain
5.Minimum baseline pain rating of 60 mm on the VAS in the primary region of pain
6.In the opinion of the investigator, the subject is psychologically appropriate for the implantation for an active implantable medical device
7.Subject is able to provide written informed consent
8.Subject speaks Dutch or English

Exclusion criteria

1.Female subject of childbearing potential is pregnant/nursing, plans to become pregnant or is unwilling to use approved birth control
2.Escalating or changing pain condition within the past month as evidenced by investigator examination
3.Subject has had corticosteroid therapy at an intended site of stimulation within the past 30 days
4.Subject has had radiofrequency treatment of an intended target DRG(s) within the past 3 months
5.Subject currently has an active implantable device including ICD, pacemaker, spinal cord stimulator or intrathecal drug pump
6.Subject has pain only or primarily within a cervical dermatomal distribution
7.Subject is unable to operate the device
8.Subjects with indwelling devices that may pose an increased risk of infection
9.Subjects currently has an active infection
10.Subject has, in the opinion of the investigator, a medical comorbidity that contraindicates placement of an active medical device
11.Subject has participated in another clinical investigation within 30 days

12.Subject has a coagulation disorder or uses anticoagulants that, in the opinion of the investigator, precludes participation
13.Subject has been diagnosed with cancer in the past 2 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-04-2012
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-06-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-08-2012
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-01-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL39022.100.12