A novel neuromodulation technique in the treatment of chronic pain.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26726

Source
NTR

Health condition

Chronic Neuropathic Pain

Sponsors and support

Primary sponsor: Spinal Modulation, Inc.
1135 O'Brien Dr.
Menlo Park, CA 94025
USA
Source(s) of monetary or material Support: Spinal Modulation, Inc.
1135 O'Brien Dr.
Menlo Park, CA 94025
USA

Intervention

Outcome measures

Primary outcome

1. Device Safety as determined by adverse event reporting. Adverse event profiles are expected to be similar to currently approved devices. These can include infection, lead

migration, etc;

2. Device Performance as indicated by programmed outputs and the ability of the subject to control paresthesias.

Secondary outcome

1. Pain relief (VAS);

2. Quality of Life (EQ-5D).

Study description

Background summary

N/A

Study objective

N/A

Study design

Multiple time points will be included in the follow-up. These timepoints include before and 1, 3, 6 and 12 months following implantation.

Intervention

This intervention involves the placement of epidural leads that provide stimulation. Stimulation intensity and the amount of of stimulation during the day is controlled by the subject to the desired levels during the duration of the clinical trial. The mechanism of action is unknown. Subjects will be followed up for 12 months following implantation neurostimulator system. Trial duration is expected to be approximately 15-18 months.

Contacts

Public
Spinal Modulation, Inc.
1135 O'Brien Dr.
Jeffery Kramer
Menlo Park CA 94025

USA
+1 650 543 6800
Scientific
Spinal Modulation, Inc.
1135 O'Brien Dr.
Jeffery Kramer
Menlo Park CA 94025
USA
+1 650 543 6800

Eligibility criteria

Inclusion criteria

1. Male or female ≥ 18 years old;

2. Chronic, intractable pain in the thoracic, lumbar, and/or sacral distributions(s) for at least 6 months;

3. Failed conservative treatments for chronic pain including but not limited to pharmacological therapy, physical therapy, and interventional pain procedures for chronic pain;

4. Minimum baseline pain rating of 60 mm on the VAS;

5. Stable pain medication dosage for at least 30 days;

6. Stable neurologic function in the past 30 days.

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 is currently involved in medically related litigation;

4. Subject currently has an active implantable device including ICD, pacemaker, spinal cord stimulator or intrathecal drug pump;

5. Subject currently has an active infection;

6. Subject has, in the opinion of the investigator, a medical comorbidity that contraindicates placement of an active medical device;

7. Subject has a coagulation disorder or uses anticoagulants that, in the opinion of the investigator, precludes participation;

8. Imaging (MRI, CT, x-ray) findings within the last 12 months that, in the investigator's opinion, contraindicates lead placement.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2011
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	27-03-2011
Application type:	First submission

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
NTR-new	NL2695
NTR-old	NTR2825
Other	Spinal Modulation, Inc. : 01-SMI-2010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A