A Multi-Center Controlled Study to characterize the real-world outcomes of High Rate Spinal Cord Stimulation therapy using Boston Scientific (BSC) PRECISION Spinal Cord Stimulator System

Published: 27-10-2016
Last updated: 17-04-2024

The primary objective of this study is to characterize the real-world outcomes of high rate spinal cord stimulation (HR-SCS) therapy as an aid in the management of chronic intractable pain of the trunk, including unilateral or bilateral pain...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON42937

Source
ToetsingOnline

Brief title
VELOCITY

Condition

- Spinal cord and nerve root disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
continued back pain after surgery, Difficult to treat low back pain

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Group plc.
Source(s) of monetary or material Support: Bedrijven

Intervention

Keyword: Failed Back Surgery Syndrome, High Rate Spinal Cord Stimulation, Low Back Pain

Outcome measures

Primary outcome

Low back pain responder rate at 3 months post-activation as compared with

Baseline. A responder is defined as *30% low back pain reduction from Baseline

without change in opioids.

Secondary outcome

Secundary endpoints:

Change in average low back pain from Baseline to 3 months post-Activation

(Numeric Rating Scale)

Change in average leg pain from Baseline to 3 months post-Activation (NRS)

Percent pain relief of low back pain at 3 months post-Activation

Percent pain relief of leg pain at 3 months post-Activation

Change in low back pain with activity from Baseline to 3 months post-Activation

(NRS)

Change in leg pain with activity from Baseline to 3 months post-Activation (NRS)

Patient global impression of change at 3 months post-Activation

Change in disability from Baseline to 3 months post-Activation (ODI v2.1a)

Change in quality of life from Baseline to 3 months post-Activation (SF-36v2)

Exploratory endpoints:

Change in average low back pain from Baseline through 6, 12 months post-Activation (NRS)

Change in average leg pain intensity from Baseline through 6, 12 months post-Activation (NRS)

Change in low back pain intensity with activity from Baseline through 6, 12 months post-Activation (NRS)

Change in leg pain intensity with activity from Baseline through 6, 12 months post-Activation (NRS)

Percent pain relief of low back pain through 6, 12 months post-Activation

Percent pain relief of leg pain through 6, 12 months post-Activation

Change in average daily leg pain intensity (NRS) from Baseline through 3, 12 months post-activation (Diary)

Change in average daily low back pain intensity (NRS) from Baseline through 3, 12 months post-activation (Diary)

Change in disability from Baseline Visit through 6, 12 months post-Activation (ODI v2.1a)

Patient global impression of change through 6, 12 months post-Activation

Change in quality of life from Baseline Visit through 6, 12 months post-Activation (SF-36v2)

Change in opioid prescription from Baseline through 6, 12 months post-Activation (Concomitant Medications)

Health economic endpoint:

Economic value of HR-SCS at 12 months post-Activation (RUI, SF-36v2,

Concomitant Medications, Procedure Information)

Safety parameter:

Rate of occurrence of all device or procedure related adverse events (AEs),

SAEs including serious adverse device events (SADEs), unanticipated serious

adverse device effects (USADEs) through end of study.

Study description

Background summary

This study will investigate the effect of High Rate Spinal Cord Stimulation (HR-SCS) in the treatment of chronic intractable low back pain.

Chronic intractable pain is often defined as pain persisting for at least 6 months which has not responded to conservative treatment(s). The pain may be due to current or past nerve injury and causes significant disability, reduced work productivity, reduced quality of life, and significant cost burden. Early treatments for chronic pain typically include over the counter and prescription medications. Later treatments like physical therapy and interventional pain procedures (e.g. intraspinal injections, vertebroplasty, pulsed RF) are attempted, sometimes followed by chronic high dose opioids and back surgery, if indicated. If back surgery is unsuccessful in relieving the chronic pain, the patient can be labeled as having failed back surgery syndrome (FBSS).

SCS is an option in the well-selected patient with chronic low back and/or leg pain. SCS is has proven to be effective for chronic intractable pain associated with a variety of conditions, including, but not limited to, FBSS, complex regional pain syndrome, and low back pain and leg pain. SCS is a less invasive treatment option for FBSS but has generally been reserved for patients who have failed multiple, and indeed all possible, repeat operations.

Spinal cord stimulation as a treatment for chronic pain has been utilized since the 1960s. Stimulation is delivered on a pulsatile basis, with frequencies of pulse delivery typically programmed between 2 and 1200 Hz (1Hz = 1 pulse per second).

High-Frequency (up to 10 kHz) spinal cord stimulation has been evaluated in chronic pain patients. Nevro Corporation*s Senza* System (Menlo Park, CA) delivers electrical stimulation at higher rates than conventional SCS devices (Smet et al., 2011 a&b; Van Buyten et al., 2011). Data from previous European clinical studies suggest that Nevro*s therapy may be effective in treating leg and back pain and other challenging types of chronic pain that often do not respond to conventional spinal cord stimulation (Smet et al., 2011 a&b; Van Buyten et al., 2011). These data also indicate significant and sustained pain reduction in patients with chronic back and leg pain.

Boston Scientific*s Precision SCS System with MultiWave Technology is capable of providing stimulation at rates up to 10 kHz. The purpose of this study is to characterize the real-world outcomes of HR-SCS therapy as an aid in the management of chronic intractable pain of the trunk, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain using the Boston Scientific (BSC) PRECISION Spinal Cord Stimulator System with MultiWave Technology.

Study objective

The primary objective of this study is to characterize the real-world outcomes of high rate spinal cord stimulation (HR-SCS) therapy as an aid in the management of chronic intractable pain of the trunk, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain using the Boston Scientific (BSC) PRECISION Spinal Cord Stimulator System with MultiWave Technology.

Study design

The study is a prospective, multi-center, single-arm study. This is a post CE mark study, within the indications for use.

Intervention

Routine implantation of the Boston Scientific*s Precision SCS System with MultiWave Technology

Study burden and risks

Subjects who take part in this study are subject to similar risks shared by all subjects who receive this device but are not participating in this study. In addition, this study is set up to collect data through questionnaires and interviews. To complete these additional questionnaires and interviews the subject will spend additional time at the hospital and/or doctor*s office. They may have an increased number of visits to the hospital and/or doctor*s office compared to standard of care.

The study subject may find it difficult, uncomfortable, or tiresome to complete study visits,diary, and/or questionnaires. They may be uncomfortable with the medication lock requirements.

The reported benefit of the PRECISION SCS System with MultiWave Technology may include:
-Reduction in the intensity of chronic low back pain
-Reduction in the intensity of chronic leg pain
-Improvement in physical functioning (disability)
-Reduction in pain-related medication use
-Reduction in the occurrence of side-effects of pain-related medications accompanied by reduction in opioid use (e.g. sleep disturbances, constipation, reduction in mental acuity)

Contacts

Public
Boston Scientific Group plc.

Gaetano Martinolaan 50
Maastricht 6229 GS
NL
Scientific
Boston Scientific Group plc.

Gaetano Martinolaan 50
Maastricht 6229 GS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Complaint of persistent or recurrent low back pain for at least 180 days prior to Screening
-No back surgery within 6 months prior to Screening
-Average low back pain intensity of 6 or greater on a 0-10 numerical rating scale during Screening (NRS) as evaluated by interview
-Baseline Oswestry Disability Index score >40 and <81
-18 years of age or older when written informed consent is obtained

Exclusion criteria

-Average leg pain is greater than or equal to average low back pain during Screening (NRS).
-Radiographic evidence of spinal instability requiring fusion
-Require implantation of lead(s) in the cervical epidural space
-Requires implantation of paddle-style SCS lead(s) via a laminotomy and/or laminectomy
-Previous spinal cord stimulation trial or is already implanted with an active implantable device(s) (e.g. pacemaker, drug pump, implantable pulse generator)

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):	17-11-2016
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Boston Scientific Precision Spinal Cord Stimulator System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-10-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-01-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL56750.091.16

Study results

Date completed:	26-04-2019
Actual enrolment:	6