MulTi-center prospectIve study determining the sustainability of pain relief and psychosocial and functional responses when utilizing a multiple waveform enabled neurostimulator

Published: 15-05-2017
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The purpose of the clinical study is to demonstrate sustainable pain control and positive psychosocial and functional effects using a neuromodulation system using Burst stimulation

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46110

Source
ToetsingOnline

Brief title
Triumph Study

Condition

- Other condition

Synonym
Chronic Pain

Health condition

Chronische pijnklachten

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: St Jude Medical

Intervention

Keyword: Burst stimulation, Chronic pain, Pain relief, Spinal cord stimulation

Outcome measures

Primary outcome

The primary objective is to evaluate sustainable pain relief with a multiple

waveform enabled neurostimulator.

Secondary outcome

The secondary objectives are to evaluate the psychosocial and functional

responses to burst and tonic stimulation.

Study description

Background summary

Spinal cord stimulation (SCS) is a minimally invasive and reversible procedure in which electrical leads are placed in the epidural space, applying stimulation to the large myelinated fibers of the dorsal column. SCS is becoming an increasingly popular alternative for the treatment of chronic, intractable pain.
A systematic review and meta-analysis of SCS in refractory neuropathic back and leg pain documented that SCS reduces pain, improves quality of life, reduces analgesic use, allows some patients to return to work, and may also result in significant cost savings over time, while having minimally significant adverse events.
In an effort to continue to optimize neurostimulation treatment and provide patients with options, the Prodigy (MRI)* and Proclaim EliteTM system have been developed.
Both systems enable the use of both tonic stimulation and Burst stimulation.

With tonic stimulation the pulse is delivered at the same amplitude, frequency and pulse width and typically produces paresthesia (tingling sensation) over the patient*s area of pain.
During burst stimulation groups of pulses called bursts trains are repeated at a burst rate; within each burst train; several pulses are issued at an intra-burst rate.Individual pulses are characterized by a pulse amplitude and pulse width in exactly the same manner as in tonic Stimulation. The amplitudes used for Burst programming are reported to be significantly lower than those traditionally used for tonic Stimulation which often results in paresthesia free therapy with continued pain suppression.
Pain stimuli are likely processed in parallel by two pathways: the lateral discriminatory pathways that helps to identify the location, type and intensity of pain and the medial affective/attentional pathway that helps to drive attention and salience to the pain
The current working hypothesis is that Burst stimulation may exert its main effect through an ability to modulate both lateral & medial pathways whilst tonic stimulation only affects the lateral pathway.
The purpose of the proposed clinical study is to collect data to evaluate sustainable pain control by using a neuromodulation system which enables both tonic and Burst stimulation.

Study objective

The purpose of the clinical study is to demonstrate sustainable pain control and positive psychosocial and functional effects using a neuromodulation system using Burst stimulation

Study design

A prospective, multicenter, single arm intervention study

Study burden and risks

There are no additional risks. The burden consists of a number of additional questionnaires.

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

1. Subject has chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome and intractable low back and leg pain.
2. Subject has a score of 6 or higher on the NRS for average pain specific to the area(s) of chronic pain being treated over the past 24 hours at the baseline visit.
3. Subject is considered by the Investigator as a candidate for implantation of a spinal cord stimulator system according to the system Instructions For Use.
4. Subject is 18 years of age or older at the time of enrollment.
5. Subject is willing to cooperate with the study requirements including compliance with the regimen and completion of all study visits.
6. Subject has signed and received a copy of the Ethics Committee/Institutional Review Board (EC/IRB) approved informed consent.

Exclusion criteria

1. Subject currently has a spinal cord stimulation system implanted.
2. Subject has previously failed SCS therapy (either trial system evaluation or permanent implant).
3. Subject has a primary diagnosis of Peripheral Vascular Disease (PVD), Angina Pectoris, or Chronic Migraine.

4. Subject has or plans to have a Peripheral Nerve Stimulation system (PNS), Peripheral Nerve field Stimulation system (PNfS), Dorsal Root Ganglion system (DRG), or implantable infusion pump.
5. Subject is currently participating in another clinical investigation with an active treatment arm.
6. Subject unable to read and/or write.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Ethics review

Not approved

Date:	15-05-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL58153.078.16