Randomized, ControlleD, Single Blinded, ProspEctive, MuLtIcenter Study EValuating Anatomic versus Targeted lead placement for Burst DR Therapy during the Trial Evaluation period

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The primary objective of this clinical investigation is to demonstrate that the qualification rate with anatomic lead placement is non-inferior to the qualification rate with targeted lead placement (tonic paresthesia guided) for the BurstDRTM trial…

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

Summary

ID

NL-OMON45537

Source
ToetsingOnline

Brief title
Delivery

Condition

- Other condition

Synonym
Chronic pain

Health condition

chronische hardnekkige pijn in romp en/of ledematen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anatomical lead placement, Spinal Cord Stimulation, Targeted lead placement, Trial stimulation

Outcome measures

Primary outcome

The primary endpoint is the qualification rate for permanent system implant at

the end of the initial trial evaluation period

Qualification for permanent system implant is defined by a composite in which a

subject meets all of the following conditions:

* >50% patient reported pain relief (PRP) at the end of the trial evaluation

* The trial evaluation period lasted for a minimum of 3 days

* Physician recommends subject for permanent system implant

* Subject reports a willingness to pursue a permanent system implant

Subjects are not qualified for permanent system implant if they meet both of

the following:

* *50% PRP (patient reported pain relief) at the end of the trial evaluation

* Trial evaluation period lasted for a minimum of 5 days

Secondary outcome

The secondary endpoint is the rate of physician preference for anatomic

placement versus targeted placement at the end of the study.

Study description

Background summary

Spinal cord stimulation (SCS) is a common therapy for the treatment of chronic, intractable pain.Typically, patients who are candidates for spinal cord stimulation have failed other treatment options and are recommended by their physician to participate in a spinal cord stimulation trial (powered by an external generator) prior to receiving a permanent implant (powered by an implantable pulse generator).This is done so that the patient can determine whether the therapy relieves pain before undergoing a procedure to implant a permanent device.
The trial consists of implanting trial electrode(s) or lead(s) into the epidural space. The lead(s) may then be connected to an external generator, allowing a trial period of stimulation.Current trial systems use external generators in which the lead(s) are connected to via additional extension wires that are tapped to the patient*s back.
St. Jude MedicalTM Invisible Trial System is using an External Pulse Generator (EPG) and Patient Controller that communicates wirelessly with each other eliminating the need for connector wires. The EPG is significantly smaller than other systems available on the market and may be bandaged to the patient*s back in the place of connector wires.
St. Jude MedicalTM Invisible Trial System enables 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 stimualtion 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 stimulation are reported to be significantly lower than those traditionally used for tonic stimulation which results in stimulation sensation free therapy with continued pain suppression.
Lead placement can be done using two different techniques; targeted lead placement, in this case the patient is tonic stimulated during placement and the patient can tell where the stimulation sensation is felt. this is where the lead will be placed. The second technique is anatomic lead placement. In this case the lead is placed between vertbrae Th7 and Th10 without any testing or stimulation.

Study objective

The primary objective of this clinical investigation is to demonstrate that the qualification rate with anatomic lead placement is non-inferior to the qualification rate with targeted lead placement (tonic paresthesia guided) for the BurstDRTM trial evaluation period.

Study design

A randomized, controlled, single blinded, multi-centered study

Intervention

SCS trial stimulation

Study burden and risks

The risks of participating in the study are virtually the same as the risks of a normal trial stimulation period for the treatment of chronic pain. In this study different methods for leadplacement are compared with each other, but this does not increase the risk for the participant.

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. Patient is indicated for SCS therapy in accordance with the approved labeling.
2. Patient*s pain profile indicates appropriate lead placement would be at one or more levels from T7 to T10, to achieve pain coverage.
3. Patient has a baseline score on the NRS *6 over the past 24 hours for *average overall pain* specific to the area(s) of chronic pain that will be treated with spinal cord stimulation.
4. Patient is considered by the Study Investigator as a candidate for implantation of a spinal cord stimulator system according to the system Instructions for Use.
5. Patient is >18 years of age at the time of enrollment.
6. Patient is willing to adhere to the study requirements, including compliance with and completion of all study visits.
7. Patient has signed and received a copy of the EC/IRB approved informed consent.

Exclusion criteria

1. Patient currently has a spinal cord stimulation system implanted.
2. Patient has previously failed a spinal cord stimulation therapy (either trial system evaluation or permanent system implant).
3. Patient has a primary diagnosis of Peripheral Vascular Disease (PVD), Angina Pectoris, or Chronic Migraine.
4. Patient is scheduled to undergo an on-the-table trial evaluation (aka all-in-one procedure).
5. Patient is scheduled to be implanted with (a) surgical paddle trial lead(s).
6. Patient is currently participating in another clinical investigation with an active treatment arm.
7. Patient is unable to read and/or write.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2018
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Invisible Trial System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-02-2018
Application type:	First submission
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	NL58717.091.16