Directional Lead: Investigation of Rotational Current Steering, Ease of Use of Clinical Effects Map, and Therapeutic Outcomes of Deep Brain Stimulation

Published: 11-07-2017
Last updated: 31-12-2024

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Ethical review	Approved WMO
Status	Completed
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON46916

Source
ToetsingOnline

Brief title
DIRECT-DBS

Condition

- Movement disorders (incl parkinsonism)

Synonym
movement disorder that affects the brain and results in shaking and/or stiffness of certain body parts, parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Cooperation International
Source(s) of monetary or material Support: industry - Boston Scientific

Intervention

Keyword: deep brain stimulation, directional stimulation, parkinson's disease

Outcome measures

Primary outcome

Due to the exploratory nature of the study no formal primary endpoints have been defined. Collected data will be used to guide product development and to build early experience to define the best practice for programming.

Secondary outcome

Exploratory endpoints are:

• Amplitude (mA) of stimulation induced side effect threshold during intra-operative testing.

• Amplitude (mA) difference between efficacy threshold for control of rigidity and first limiting stimulation induced side effect threshold, i.e. *therapeutic window*, for all evaluated settings at Programming Visits - Day 1, 2 and 3

• UPDRS III Scores for selected settings at Programming Visits - Day 1, 2 and 3 and at Randomization, Crossover, Release, and 1 Year Follow Up Visits

• Kinesia ONE scores for selected settings at Programming Visits - Day 1, 2 and 3 and at Randomization, Crossover, Release, and 1 Year Follow Up Visits

• PDQ-39 Scores at Randomization, Crossover, Release, and 1 Year Follow Up Visits

• Kinesia 360 motor diary scores during Crossover Arms 1 and 2

Study description

Background summary

This study will compare various program settings for the bilateral stimulation of the subthalamic nucleus using the Boston Scientific's implantable Vercise* PC Deep Brain Stimulation System for the treatment of levodopa-responsive, moderate to severe idiopathic PD. The Vercise* PC System is capable of delivering stimulation similar to other commercially available DBS systems. However, the Vercise* PC System combined with the directional lead also features an expanded parameter range when compared to commercially available conventional cylindrical electrodes, including the ability to shape stimulation in the plane orthogonal to the long axis of the lead ("directional stimulation"), and at settings that utilize independent current sources for multiple contacts (*current steering*).
This study aims to characterize the effects of directional stimulation in subjects implanted with this novel technology.

Study objective

The primary objective is to characterize the programming effects of Boston Scientific Vercise* PC System using the Deep Brain Stimulation Directional Lead for bilateral subthalamic nucleus DBS for the treatment of Parkinson*s disease in acute and chronic settings.
The exploratory objectives are to evaluate the directional marker, changes in impedance over time, collect induced field potentials and to explore sensitivity to current steering settings. In addition, to assess use and usefulness of the Vercise* Navigator Steering mode controls and Clinical Effects Scores capture in the Directional Lead Clinical Effect Maps on the Vercise* Programmer.

Study design

Prospective, multi-center, open label study with double-blinded exploratory and crossover phases. This is a post CE-mark study within the indications for use.

Intervention

Routine implantation of Boston Scientific's Vercise* PC Deep Brain Stimulation System with the directional lead

Study burden and risks

Patients who have DBS for Parkinson*s disease but are not in this study share similar risks associated with the implant procedure and deep brain stimulation

therapy.
The following risks maybe associated with patients* participation in the clinical study:
• Subjects may find it difficult, uncomfortable, or tiresome to complete study visits, study-diaries and questionnaires.
• Subjects may experience various symptoms related to the temporary withdrawal of Parkinson medications and withdrawal of neurostimulation, which is a condition required of specific study visits. Symptoms may include, but are not limited to, worsening of Parkinson*s disease signs, apathy, anxiety, disturbance in cognition, or changes in sleep. In addition, the discontinuation of Parkinson medications is associated with a remote risk of developing a life-threatening condition known as neuroleptic malignant syndrome.
• As various deep brain stimulation settings are tested, subjects may experience side effects including, but not limited to, a sensation of tingling, muscle spasm, change in speech, mood, vision, cognition, disturbance of balance, coordination, tremor, dizziness.
• Subjects with postural instability or gait disturbances either due to their Parkinson*s disease or as a side effect of DBS may be at a risk of falling while completing motor tasks as required for certain study assessments.

To complete the study measurements, subjects will spend additional time at the hospital and/or doctor's office including some visits that may not be per center's standard of care.

As the potential benefit for the study subject, the study doctor might get extra insights from the study-related measurements that can be used to optimize the stimulation settings for subject's therapy, potentially resulting in improved clinical outcomes and/or reduced side effects.

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

IC1. Candidate for Vercise* PC DBS with bilateral implant of BSN DBS Directional Leads in STN, and meets:
• Diagnosis of bilateral idiopathic PD with the presence of rigidity and at least one (1) of the following: resting tremor or bradykinesia.
• UPDRS III score of >25 in the meds OFF condition
• Medication must improve PD symptoms by >=30%, as measured by UPDRS subset III score
IC2. Willing and able to comply with all visits, including required travel, and with study related procedures
IC3. Meets all requirements of Vercise* PC Local Directions For Use (DFU)
IC4. Able to understand the study requirements and the treatment procedures and provides written informed consent before any study-specific tests or procedures are performed

Exclusion criteria

EC1. Any significant psychiatric problems, including unrelated clinically significant depression as determined by the investigator
EC2. Any current drug or alcohol abuse as determined by the investigator
EC3. Any history of recurrent or unprovoked seizures
EC4. Any significant medical condition that is likely to interfere with study procedures or likely to confound evaluation of study endpoints, including any terminal illness with survival <12 months

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-09-2017
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	Vercise PC deep brain stimulation system with directional lead
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-07-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL57033.018.16

Study results

Date completed:	19-12-2018
Results posted:	09-10-2019
Actual enrolment:	4

First publication
17-09-2019