Prospective Study of Deep Brain Stimulation with the VERCISE* System for treatment of Dystonia

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON52442

Source
ToetsingOnline

Brief title
Vercise DBS Dystonia Prospective Study

Condition

- Movement disorders (incl parkinsonism)
- Nervous system, skull and spine therapeutic procedures

Synonym
Dystonia, movement disorder

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Benelux
Source(s) of monetary or material Support: Bedrijven

Intervention

Keyword: Deep Brain Stimulation, Dystonia, Prospective study

Outcome measures

Primary outcome

Clinical endpoints:

The following clinical endpoints will be analyzed for each sub-group of dystonia separately (Primary vs. Secondary):

• Proportion of subjects with 30% or greater reduction in Baseline BFMDRS or TWSTRS score at 26 weeks, 52 weeks, 2 years, and 3 years post implant procedure

• Change in BFMDRS scores from Baseline to 26 weeks, 52 weeks, 2 years, and 3 years post implant procedure

• Change in TWSTRS scores from Baseline to 26 weeks, 52 weeks, 2 years, and 3 years post implant procedure

• Change in SF-36v2 score (SF-10v2 in patients under the age of 18 years at the time of consent) from Baseline to 26 weeks, 52 weeks, 2 years, and 3 years post implant procedure

• Change in GDS scores from Baseline to 26 weeks, 52 weeks, 2 years, and 3 years post implant procedure

• Clinical Global Impression of Change (CGI-C) rating score, as assessed by neurologist, at 26 weeks, 52 weeks, 2 years, and 3 years post implant procedure

• Clinical Global Impression of Change - Subject (CGI-C: Sub), as assessed by subject, at 26 weeks, 52 weeks, 2 years, and 3 years post implant procedure

• Clinical Global Impression of Change - Caregiver (CGI-C: Crg), as assessed by

caregiver, at 26 weeks, 52 weeks, 2 years, and 3 years post implant procedure

Secondary outcome

Safety parameters:

Rates of occurrence of all serious adverse events (SAEs) and all adverse device effects (ADEs), including serious adverse device effects (SADEs) and unanticipated serious adverse device effects (USADEs) at 3 years post implant procedure

Heatlh economics endpoints:

• Total cost of treatment and resource utilization from Baseline through end of study (RUI)

• Change in economic value from Baseline to 26 weeks, 52 weeks, 2 years and 3 years post implant procedure

Study description

Background summary

Dystonia is a neurological condition characterized by involuntary movements and muscle spasm. Dystonia is an umbrella term covering a broad spectrum of conditions, which can be classified depending on the cause, body areas affected and age of onset of the dystonia. Idiopathic dystonia is estimated to be the third most frequent movement disorder after essential tremor and Parkinson's disease.

Typically the initial treatment consists of medical therapy and injections of muscle relaxing medications. In the past, for subjects who experienced reduced response to the medical therapy, often surgical procedures were performed creating irreversible lesions in the brain.

Due to the introduction of reversible and more patient specific adjustable treatments, such as deep brain stimulation, these surgical procedures are now

considered less advantageous.

Since the 2000s, the safety and efficacy of deep brain stimulation for the treatment of dystonia has been demonstrated repeatedly by randomized clinical trials and case studies. The current registry will follow a large group of patients who were implanted according to the standard of care for 3 years.

Study objective

In 2013 the Boston Scientific VERCISE System has obtained regulatory approval for use in the European Union, CE mark was granted for the treatment of intractable primary and secondary dystonia.

The objective of the study is to compile characteristics of real-world outcomes, economic value and technical performance of Boston Scientific Corporation's commercially approved VERCISE deep brain stimulation system, when used according to applicable Directions for Use.

Study design

Prospective, on-label, multi-center, international study. Study of a CE marked device within the approved indications.

Study burden and risks

Subjects who take part in this study are subject to similar risks shared by all subjects who receive this stimulator but are not participating to this study. In addition, this study is set up to collect data through questionnaires and interviews. The questionnaires and interviews will take place during routinely scheduled follow up visits but they are, depending from study center to study center, not always routinely taken. Because of participation to the study, the follow up visits will take additional time as compared to routine care, which could be uncomfortable to the subject.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

-Subject meets criteria established in the locally applicable VERCISE System Directions for Use (DFU) for dystonia
-Subject is at least 7 years old. Parent or guardian consent is required in patients who are younger than 18 years at the time of consent

Exclusion criteria

Subject meets any contraindication in the VERCISE System locally applicable Directions for Use

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-05-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Vercise DBS System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-07-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	01-07-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-04-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT02686125
CCMO	NL70665.058.19