# Study to Evaluate Boston Scientific VerciseTM CartesiaTM 16-contact Directional Lead (X/HX) with Deep Brain Stimulation (DBS) Systems for the treatment of Parkinson*s Disease (PD)

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To document patient outcomes including effectiveness for Boston Scientific Corporation*s VerciseTM CartesiaTM 16-contact Directional Lead (X/HX) with Deep Brain Stimulation (DBS) Systems for the treatment of Parkinson*s Disease (PD).

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

## Summary

### ID

NL-OMON52786

**Source**
ToetsingOnline

**Brief title**
Cartesia eXTend 3D Study

### Condition

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

**Synonym**
movement disorder, Parkinson's disease

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Boston Scientific International BV
**Source(s) of monetary or material Support:** Boston Scientific

## Intervention

**Keyword:** Cartesia, Deep Brain Stimulation, Parkinson's Disease

## Outcome measures

### Primary outcome

Mean change in MDS-UPDRS III scores from Baseline in meds off condition to 12 weeks post device-activation in stim on/meds off condition.*

*Note: during baseline visit and follow up visits, UPDRS-II and UPDRS-III assessments will be performed in meds ON and meds OFF condition. The study subjects will be asked to discontinue anti-Parkinson medication 12 hours before each visit (or 24 hours before each visit for long acting anti-Parkinson medication). When the meds OFF assessments are performed, the subject will be asked to start the anti-Parkinson medication again, after which the meds ON assessments will take place.

### Secondary outcome

Secondary endpoints:

The following secondary endpoints will be analyzed. Study assessments in parenthesis.

- Mean change in MDS-UPDRS III scores from Baseline (meds off) to 26 weeks and 52 weeks post device-activation (stim on/meds off)

- Mean change in PDQ-39 summary scores from Baseline (meds on) to 12 weeks, 26

weeks and 52 weeks post device-activation (stim on/meds on)

- Mean Change in antiparkinsonian medication use (levodopa equivalents) from Baseline to 12 weeks, 26 weeks and 52 weeks post device-activation

- Clinical Global Impression of Change (CGI-C) rating score, as assessed by clinician at 12 weeks, 26 weeks and 52 weeks post device-activation

- Clinical Global Impression of Change - Subject (CGI-C: Sub), as assessed by subject, at 12 weeks, 26 weeks and 52 weeks post device-activation

Exploratory endpoints:

The following exploratory endpoints will be analyzed. Study assessments in parenthesis

- Mean change in MDS-UPDRS III scores from Baseline (meds off) up to 5 years post device-activation (stim on/meds off)

- Mean change in PDQ-39 summary scores from Baseline (meds on) up to 5 years post device-activation (stim on/meds on)

- Mean Change in antiparkinsonian medication use (levodopa equivalents) from Baseline up to 5 years post device-activation

- Clinical Global Impression of Change (CGI-C) rating score, as assessed by clinician up to 5 years post device-activation

- Clinical Global Impression of Change - Subject (CGI-C: Sub), as assessed by subject up to 5 years post device-activation

- Mean Change in SE scores from Baseline up to 5 years post device-activation

- Mean in MDS-UPDRS scores (Part I, II, III, IV, and total score), from Baseline (meds on) up to 5 years post device-activation (stim on/meds on)

Safety parameters:

Rates of occurrence of all device hardware, device stimulation and procedure related non-serious adverse events, all serious adverse events, (regardless of relationship), and unanticipated serious adverse events through the end of the study.

# Study description

**Background summary**

Parkinson*s disease (PD) is a progressive neurodegenerative disorder that affects 5.2 million people worldwide. The prevalence of PD is estimated at 0.3% of the overall population in industrialized countries and advances to 1% by age 60 and 4% in the highest age group.

At present there is no cure for PD; treatment is focused on medical management of motor symptoms. Medical therapy has been primarily focused on restoring dopamine levels. Current standards for patient care recommend levodopa as first line of therapy for the symptomatic control during the early, uncomplicated stages. Unfortunately, chronic treatment with levodopa frequently leads to significant side effects.

In the 1990s, high-frequency deep brain stimulation (DBS) was demonstrated to be effective in reducing the motor complications of subjects with PD . Since that time, numerous case studies and trials have substantiated these early findings.

Recent advances in technology including directional stimulation has the potential to further improve patient outcomes. Several pilot studies have corroborated the use of directionality and its impact on therapeutic window and adverse effects.

The directional leads used in this study consist of 16 contacts, the existing commercially available directional leads have 8 contacts. The 16-contact leads extend the span of contacts when compared with commercially available directional leads.

The programming options with the Vercise* Cartesia* 16-contact Directional Leads potentially improve therapy and/or reduce stimulation-related side effects are anticipated to be perceived as benefits.

This study will document patient outcomes including effectiveness for Boston Scientific Corporation*s VerciseTM CartesiaTM 16-contact Directional Lead (X/HX) with Deep Brain Stimulation Systems for the treatment of Parkinson*s Disease.

## Study objective

To document patient outcomes including effectiveness for Boston Scientific Corporation*s VerciseTM CartesiaTM 16-contact Directional Lead (X/HX) with Deep Brain Stimulation (DBS) Systems for the treatment of Parkinson*s Disease (PD).

## Study design

Prospective, multi-center, open-label study with an adaptive design.

## Intervention

The intervention exists of the implantation of/with the Vercise* Cartesia* X/HX 16-contact Directional Leads, 16-contact Lead Extensions and 16-contact Push Button OR Cable, instead of commercially available directional leads and cables.

## Study burden and risks

Risks related to the study specific questionnaires:
The study specific outcomes are mainly collected by means of questionnaires and interviews during routine visits and study specific visits. The questionnaires and interviews do not pose the subject to any risks, but subjects may find it difficult, uncomfortable, or tiresome to complete study visits and/or questionnaires, including discomfort during *meds off* or *meds on* conditions for testing (UPDRS on 12 weeks, 26 weeks, 2 - 3 - 4 year post activation is not standard of care).

Risks related to the study specific assessments:
Subjects with postural instability or gait disturbances either due to Parkinson*s disease or as a side effect of DBS may be at a risk of falling while walking, rising from a chair, or sitting down in a chair as required for certain study assessments (UPDRS). The UPDRS is evaluated routinely in meds ON and meds OFF condition at all protocol time points, subject to the 12 week, 26 week, 2 - 3 - 4 year follow up visit (as these time points are study specific). The additional risk due to participation to the study is therefore limited.

Risks related to the surgical intervention:
Subjects participating in this study have the same risks for DBS as those who have DBS for treatment of PD outside of the study. Because the handling characteristics of the VerciseTM CartesiaTM 16-contact Directional Leads are

similar to those of commercially-available leads, it is expected that the type and rate of lead-related adverse events will be similar for both kinds of leads.

Risks associated with the study leads / extensions / OR cable:
There are no additional known risks associated with the investigational device in comparison to commercially-available devices.

Possible interactions with concomitant medical treatments:
While concomitant use of anti-Parkinson medications is being adjusted to fit the subject*s changed requirements with use of DBS, subjects may experience symptoms beyond those occurring due to Parkinson*s disease.

In summary, the burden and risks associated with participation to the study are mainly related to the completion of study specific questionnaires and motor assessments:
- UPDRS at 12 week, 26 week, 2 - 3 - 4 year follow up
- Completion of questionnaires

In het licht van deze belasting en risico's is het uitvoeren van deze studie gerechtvaardigd.

Considering the above burden and risks, the conduct of this study is justified.

## Contacts

**Public**
Boston Scientific International BV

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NL
**Scientific**
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## Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- Diagnosis of idiopathic PD with a disease duration of at least 5 years and presence of at least 2 of the following: resting tremor, rigidity, or bradykinesia
- Candidate for DBS implant in the treatment of Parkinson*s disease
- Must be on stable anti-parkinsonian medications for 28 days prior to Informed Consent
- Persistent disabling Parkinson's disease symptoms such as dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy
- Anti-parkinsonian medications must improve PD symptoms by >= 33%, as measured by MDS UPDRS-III score
- Mean MDS-UPDRS III score of >=30 in meds off condition
- DRS-2 (Dementia Rating Scale -2) score >= 130 in the meds on condition
- Be willing and able to comply with all visits and study related procedures (e.g., using the remote control, charging system, etc.).
- Able to understand the study requirements and the treatment procedures and provides written informed consent before any study-specific tests or procedures are performed
- At least 18 years of age

## Exclusion criteria

- Any intracranial abnormality or medical condition that would contraindicate DBS surgery
- Have any significant psychiatric or cognitive condition likely to compromise the subject*s ability to comply with requirements of the study protocol (e.g. bipolar, schizophrenia, mood disorder with psychotic features, cluster B personality disorders)
- Have untreated clinically significant depression per DSM-IV (Diagnostics and Statistical Manual of Mental Disorders) criteria as determined by BDI-II score >= 17
- Any current drug or alcohol abuse, as determined by the investigator

- Any history of recurrent or unprovoked seizures
- History of suicidal attempt within the last 1 year prior to consent or current active suicidal ideation as determined by the investigator
- Any significant medical condition that is likely to interfere with study procedures or likely to confound evaluation of study endpoints
- Any terminal illness with life expectancy of < 12 months
- A female who is breastfeeding or pregnant (method of assessment per investigator discretion) at the time of enrollment*, or women who plan to become pregnant during the course of the study.
- Participation in any other clinical trial (e.g. drug, device, or biologics) concurrently or within the preceding 30 days. Participation in any other study will be allowed per investigator/sponsor discretion only
*Pregnancy tests from up to 7 days prior to enrollment in the study will be accepted.

# Study design

## Design

**Study type:** Interventional

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 09-02-2021 |
| Enrollment: | 40 |
| Type: | Actual |

## Medical products/devices used

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| Generic name: | Vercise Cartesia X/HX 16-contact Directional Leads;16-contact Lead Extensions and 16-contact Push |
| Registration: | No |

# Ethics review

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| Approved WMO Date: | 15-12-2020 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 05-02-2021 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 18-05-2021 |
| Application type: | Amendment |
| 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 |
|---|---|
| ClinicalTrials.gov | NCT04577651 |
| CCMO | NL74466.018.20 |