Personalizing stimulation parameters in deep brain stimulation for Parkinson*s Disease based on disease phenotype and brain connectivity: a feasibility study

Published: 29-04-2025
Last updated: 02-05-2025

In this pilot study, we aim to assess practical feasibility, technical feasibility and safety of a computational approach for programming newly implanted STN-DBS patients with PD. This computational approach will be based on patient-specific sweet...

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

Summary

ID

NL-OMON57446

Source
ToetsingOnline

Brief title
iDBS

Condition

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

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Boston Scientific,Boston Scientific Cooperation International

Intervention

Keyword: Deep Brain Stimulation, Parkinson's disease

Outcome measures

Primary outcome

The primary endpoints are safety (occurrence of stimulation induced side-effects, duration of induced side effects (temporary or permanent), severity of the stimulation induced side-effects) and technical feasibility (time from surgery to DBS-initiation, time from surgery to reaching optimal DBS stimulation settings) of the computational workflow.

Secondary outcome

The secundary endpoints are the practical feasibility of a larger randomized trial (inclusion rate of patients meeting the inclusion criteria, withdrawal/drop-out within the study period, adherence to the research protocol with regard to the DBS programming), difference in UPDRS-III OFF-medication condition before surgery and UPDRS-III OFF-medication ON-stimulation condition at 3, 6 and 12-months follow-up between the two arms, difference in Levodopa Equivalent Daily Dose (LEDD) before surgery and at 3, 6 and 12-months follow-up between the two arms, difference in Parkinson Disease Questionnaire-39 (PDQ-39) before surgery and at 3, 6 and 12-months follow-up between the two arms, number of hospital consultations (by phone or as an outpatient) during the follow-up

period.

Study description

Background summary

Bilateral deep brain stimulation (DBS) of the subthalamic nucleus (STN) is a well-accepted treatment for advanced Parkinson*s disease (PD). Currently programming of the DBS is done in a trial-and-error manner and it can take up to 12 months to reach optimal stimulation parameters of the DBS. Technological advances in electrode design and implantable pulse generator (IPG) capabilities lead to an almost infinite number of stimulation options. To explore the potential benefit of all these technological advances, a conventional trial-and-error approach is no longer sufficient. Consequently, there is a clear need for a more computational approach of programming DBS systems. This pilot study is a prospective trial to proof that the concept of programming bilateral STN-DBS for PD in a computational fashion based on disease phenotype and brain connectivity is feasible.

Study objective

In this pilot study, we aim to assess practical feasibility, technical feasibility and safety of a computational approach for programming newly implanted STN-DBS patients with PD. This computational approach will be based on patient-specific sweet spots and connectivity of the STN. The results of this pilot study will be used to create a practically feasible computational approach for DBS programming to use in a larger randomized study in the future.

Study design

Prospective randomized pilot study.

Intervention

Patients will be randomized to receive either (i) computational DBS programming (n=12) or (ii) conventional trial-and-error based DBS programming (n=12).

Study burden and risks

We hypothesize that the proposed computational approach for DBS-programming provides PD patients with a non-inferior motor outcome compared to the conventional workflow, but that the optimal DBS settings will be reached faster using the computational based approach. All participants will need to undergo

an additional head CT scan, compared to the conventional workflow arm. The risk of the additional head CT in this patient population is negligible. Therefore, we estimate that the additional risk for patients who participate in this study is negligible.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

o Patients that are eligible for bilateral STN-DBS surgery for idiopathic PD in the Radboud university medical center
o Patients are implanted with Boston Scientific Cartesia directional leads.
o Patients have given written informed consent to participate in the study

Exclusion criteria

o Any significant medical condition that is likely to interfere with study procedures.
o Participation in any other clinical trial (e.g. drug, device, or biologics) concurrently or within the preceding 30 days.
o Lead orientation cannot be determined by GuideXT algorithm based on the new head-CT scan.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-04-2025
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	NL87334.091.24