Randomized trial comparing steered Deep Brain Stimulation with ring-shaped Deep Brain Stimulation for advanced Parkinson*s disease

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To demonstrate that steered STN DBS is more effective than ring-mode DBS in reducing PD motor symptoms and to demonstrate that steered STN DBS has the potential to cause less stimulation-induces side-effects.

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

Summary

ID

NL-OMON53065

Source
ToetsingOnline

Brief title
STEEred vs RING-mode DBS for Parkinson*s disease (STEERING) trial

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Deep Brain Stimulation, Parkinson Disease, steering, STN

Outcome measures

Primary outcome

The primary outcome measure is a score of motor symptoms in daily living as expressed in the Movement Disorders Society Unified Parkinson Disease Rating (MDS-UPDRS) motor evaluation in standardized OFF-drug phase. This score is measured in the total of all patients included, the subgroup of patients whose ring-mode stimulation has yielded a suboptimal effect (as evaluated by the patients* physician) and the subgroup of patients whose ring-mode stimulation has yielded a good effect (as evaluated by the patients* physician).The combined subgroups form the total of all included patients.

Secondary outcome

Secondary outcome consists of symptom scales, percentage of patients with great symptom improvement (an MDS-UPDRS score in OFF-phase of 30% or greater), used stimulation settings, medication use, stimulation-induced side-effects, activities of daily living scales and a quality of life questionnaire. At the end of the trial, patients will be asked to choose between the two used programs to evaluate, which one was perceived as the best. A sub-analysis will be performed to evaluate whether good DBS responders and suboptimal DBS responders score differently on primary and secondary endpoints.

Study description

Background summary

Continuous bilateral subthalamic nucleus (STN) deep brain stimulation (DBS) is an effective surgical treatment for patients with advanced Parkinson*s Disease (PD) who have severe limitations in functioning due to medication induced motor response fluctuations. Despite its effectiveness, DBS therapy is oftentimes restricted by side-effects caused by electrical current overspill into areas of the brain adjacent to the target areas. Recently, new DBS electrodes have been commercialized that claim to be able to achieve a certain degree of steering of the stimulating electrical current (steering electrodes, as opposed to the conventional ring-mode electrodes).

Study objective

To demonstrate that steered STN DBS is more effective than ring-mode DBS in reducing PD motor symptoms and to demonstrate that steered STN DBS has the potential to cause less stimulation-induces side-effects.

Study design

The study will be a randomized single-center prospective double-blind, crossover trial comparing two forms of STN deep brain stimulation settings: (1) ring-mode stimulation and (2) steered stimulation.

Intervention

After a period of searching for the optimal steered mode settings, patients will be randomized and blindly receive two different programming forms of DBS stimulation: ring mode and steered mode during two consecutive periods of two months each. The patient, the assessor and the investigator performing the statistical analyses will be blind to the order in which the two settings are administered. The patient*s physician may be unblinded if stimulation-related problems occur.

Study burden and risks

This study will contribute to the optimization of DBS treatment with devices that allow for current steering. The hardware and software that will be used in the course of the study are CE approved, and DBS has been a registered therapy for PD for years. In this study, new programming options will be explored, which will extend the device programming time. There is a small chance/risk that the steering DBS form will have less benefit to the patient*s motor score when compared to ring-mode DBS or that patients will be subjected to a longer

programming time with no additional clinical benefit. Participation in this study constitutes a negligible risk according to the NFU-criteria for human research.

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

Age >= 18 years
bilaterally implanted with the Boston Scientific or Medtronic system in the STN for idiopathic Parkinson*s Disease at least 6 months previous to study enrollment
the optimal ring-mode stimulation setting has been found for the patient: changing settings will either (a) not improve the motor scores or (b) cause stimulation-induced side-effects

Patients who have received this system by participating in the GALAXY-trial can only be randomized after completion of the GALAXY trial.

Exclusion criteria

no adequate stimulation response in ring-mode on one of the steerable levels (second and third contact point on each lead)
Legally incompetent adults
Active psychosis
No written informed consent

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-12-2017
Enrollment:	96
Type:	Actual

Medical products/devices used

Generic name:	Deep Brain Stimulation system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-08-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-12-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.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
CCMO	NL61838.018.17