Randomized trial comparing steered stimulation DBS with ring-shaped DBS for advanced Parkinson’s disease

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22973

Source
NTR

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

Health condition

Parkinson's Disease

Deep Brain Stimulation

Subthalamic Nucleus (STN)

Steering

Ziekte van Parkinson

Diepe Hersenstimulatie

Nucleus Subthalamicus

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam (AMC)
Source(s) of monetary or material Support: This study is financed by an innovation grant from the AMC Amsterdam.

Intervention

Outcome measures

Primary outcome

We will evaluate the difference of motor symptoms in patients with steered and ring-mode DBS in standardized OFF-drug phase measured with the Movement Disorders Society Unified Parkinson Disease Rating Scale motor evaluation (MDS-UPDRS-ME).

Secondary outcome

Secondary outcome consists of symptom scales, 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

Rationale: 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, possibly caused by electrical current overspill into areas of the brain adjacent to the target areas. Recently, new DBS electrodes have been developed that claim to be able to achieve a certain degree of steering of the electrical current (steering electrodes, as opposed to the conventional ring-mode electrodes).

Objective: To evaluate whether steered STN DBS is more effective than ring-mode DBS in reducing PD motor symptoms and to investigate if steered STN DBS has the potential to cause less stimulation-induces side-effects.

Hypothesis: We hypothesize that steering DBS will lead to a greater reduction of PD motor

symptoms than ring-mode DBS. We will also separately measure the effect of the two types of DBS in people who have good response to ring-mode and those who don’t.

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. A total of 102 patients will be included.

Study population: Patients with advanced PD who have been bilaterally implanted with Boston® Vercise™ DBS electrodes in the subthalamic nucleus in the AMC.

Intervention: After a period of searching for the optimal steered mode settings, patients will be randomized to receive both steered and ring-mode stimulation in consecutive periods of two months in random order. The patient, the assessor and the investigator performing the statistical analyses will be blind to the order in which the two settings are administered.

Main study parameters/endpoints: We will evaluate the difference of motor symptoms in patients with steered and ring-mode DBS in standardized OFF-drug phase measured with the Movement Disorders Society Unified Parkinson Disease Rating Scale motor evaluation (MDS-UPDRS-ME). Secondary outcome consists of symptom scales, 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

We hypothesize that steering DBS will lead to a greater reduction of PD motor symptoms than ring-mode DBS. We will also separately measure the effect of the two types of DBS in people who have good response to ring-mode and those who don’t.

Study design

• (informed consent)

• Baseline

• Visites tijdens instelperiode van “steering-settings”

• Randomisatievisite

• Cross-over visite

• Release visite

Intervention

After a period of searching for the optimal steered mode settings, patients will be randomized to receive both steered and ring-mode stimulation in consecutive periods of two months in random order. The patient, the assessor and the investigator performing the statistical analyses will be blind to the order in which the two settings are administered.

Contacts

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Eligibility criteria

Inclusion criteria

Age ≥ 18 years

bilaterally implanted with the Boston Scientific® Vercise™ 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 type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-12-2017
Enrollment:	102
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-06-2017
Application type:	First submission

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
NTR-new	NL6508
NTR-old	NTR6696
Other	METC Amsterdam : 2017_164

Study results