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

Gepubliceerd: 23-06-2017 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22973

Bron
NTR

Verkorte titel
STEEred vs RING-mode DBS for Parkinson’s disease (STEERING) trial

Aandoening

Parkinson's Disease

Deep Brain Stimulation

Subthalamic Nucleus (STN)

Steering

Ziekte van Parkinson

Diepe Hersenstimulatie

Nucleus Subthalamicus

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam (AMC)
Overige ondersteuning: This study is financed by an innovation grant from the AMC Amsterdam.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

• (informed consent)

• Baseline

• Visites tijdens instelperiode van "steering-settings"

• Randomisatievisite

• Cross-over visite

• Release visite

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Kamer H2-225

T.R. ten Brinke
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
020 566 3447

Wetenschappelijk

Kamer H2-225

T.R. ten Brinke
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
020 566 3447

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-12-2017
Aantal proefpersonen:	102
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-06-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6508
NTR-old	NTR6696
Ander register	METC Amsterdam : 2017_164

Resultaten