Apathy and DBS in Parkinson’s disease

No registrations found.

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

Summary

ID

NL-OMON22692

Source
Nationaal Trial Register

Brief title
Apathy and DBS in Parkinson’s disease

Health condition

Parkinson's Disease

Sponsors and support

Primary sponsor: Parkinsonvereniging
Source(s) of monetary or material Support: Parkinsonvereniging

Intervention

Outcome measures

Primary outcome

The primary outcome is the comparison of the SAS score following one month of DBS on the original contact and the SAS score following one month of DBS on the more dorsal contact.

Secondary outcome

Secondary outcomes are symptom changes on the Movement Disorders Society-Unified Parkinson’s Disease Rating Scale motor part III (MDS-UPDRS-III), Montgomery- Åsberg

Depression Rating Scale (MADRS), 39-item Parkinson’s disease Questionnaire (PDQ-39) Parkinson's Disease Impulsive-Compulsive Disorders Questionnaire (QUIP), changes in levodopa-equivalent daily dosage (LEDD), apathy rated by the caregiver (AES-I), and burden and quality of life of the caregiver (SF-36). Imaging data available from standard clinical care (pre-operative structural and diffusion-weighted MRI scans and post-operative CT-scan) will be used to determine the locations and white matter connections of the experimental and original stimulation contact, and to correlate this contact-specific neuroanatomical information with apathy scores and effectiveness of the intervention.

Study description

Background summary

A multicenter double blind randomized crossover study in PD patients with STN DBS, comparing severity of apathy between the experimental dorsal stimulation setting and the original stimulation settings.

Study objective

To test the hypothesis that apathy after STN DBS may be reversed by switching the activated contact on the DBS-electrode from a ventral to a more dorsal contact.

Study design

baseline, +1 month, +2 months

Intervention

26 PD patients will be randomly assigned to one of two arms. Arm-A will undergo 1 month of dorsal stimulation (intervention) followed by 1 month of regular stimulation (control). Arm-B will undergo 1 month of regular stimulation followed by 1 month of dorsal stimulation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients suffering from Parkinson’s disease.
2. At least three months of STN DBS surgery.
3. Apathy — i.e., a 14 or more points on the SAS in PD patients.

Exclusion criteria

1. Peri-operative intracerebral complications related to SNT-DBS placement (e.g., bleeding or infection) inflicting permanent changes.
2. Dementia (MOCA score of 25 or less)
3. Patients who are not sufficient in the Dutch language
4. Patients who are already stimulated on the most dorsal contact point on both electrodes
4. Legally incompetent adults
5. No signed informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Control: Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2020
Enrollment:	26

Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	10-01-2020
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	NL8279
Other	METC AMC : METC2019_150

Study results