OPTIMIzing patient selection for deep brain STimulation of the subthalamic nucleus in Parkinson’s disease: the OPTIMIST study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21813

Source
NTR

Brief title
OPTIMIST study

Health condition

Parkinson's disease, Deep Brain Stimulation, Parkinson's disease dementia (PDD)

Sponsors and support

Primary sponsor: Leiden University Medical Center, dept. of Neurology
Source(s) of monetary or material Support: Stichting Parkinson Fonds

Intervention

Outcome measures

Primary outcome

Success to STN DBS is quantified as the difference in MDS-UPDRS

motor scores measured during an acute stimulation challenge

Secondary outcome

Psychotic symptoms in the 72 hours following surgery, measured by DOS

Global satisfaction with surgery scale

SENS-PD composite score

MDS-UPDRS motor score

Cognitive decline 12 months after surgery

Study description

Background summary

Deep Brain Stimulation (DBS) of the Subthalamic Nucleus (STN) is an effective treatment for advanced Parkinson’s Disease. However, there is an increasing need to predict which patients fully benefit from DBS-STN and which will not. In a multi-center observational setting, patients undergoing DBS-STN will receive extensive motor- and non-motor assessments which can be used as potential predictors of 1-year post-operative functioning. We aim to develop a prediction model of success to DBS-STN, i.e. improvement of motor function, which ultimately aims to optimize patient selection for surgery.

Study objective

We expect to develop a robust predictive model with which to identify patients who are most likely to benefit from STN-DBS, thereby optimizing the screening procedure for DBS.

Study design

STN-DBS screening (prior to surgery)

Up to 72 hours post-surgery

One year post-surgery

Intervention

No intervention is formally tested. Patients eligible for STN-DBS after routine screening in the DBS centres will be operated on according to standard procedures. Questionnaires and rating

scales will be used for evaluation og the oucomes

Contacts

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Eligibility criteria

Inclusion criteria

Age > 18 years

Diagnosis of idiopathic Parkinson's disease

Clinical indication for STN-DBS at the participating centres

Ability to give informed consent

Ability to comply with the study assessments

Ability to read or understand Dutch

Exclusion criteria

Exclusion criteria (contra-indications) for STN-DBS:

Parkinson's disease severity: HY stage 5

Score on Mattis Dementia Rating scale <120

Psychiatric contraindications for STN-DBS

General contra-indications for stereotactic surgery and/or general anaesthesia

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-01-2017
Enrollment:	83
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-01-2017
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	NL6079
NTR-old	NTR6226
CCMO	NL ABR 58679

Study results