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

Gepubliceerd: 24-01-2017 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21813

Bron
NTR

Verkorte titel
OPTIMIST study

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center, dept. of Neurology
Overige ondersteuning: Stichting Parkinson Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Success to STN DBS is quantified as the difference in MDS-UPDRS
motor scores measured during an acute stimulation challenge

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

STN-DBS screening (prior to surgery)

Up to 72 hours post-surgery

One year post-surgery

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	31-01-2017
Aantal proefpersonen:	83
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

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

Resultaten