The microlesion effect on cognition after Deep Brain Stimulation in Parkinson’s Disease

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The hypothesis is that the microlesion effect affects cognitive functioning in Parkinson's disease patients undergoing STN-DBS.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25026

Bron
NTR

Verkorte titel
TBA

Aandoening

Parkinson's disease

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoints of the study are the SDMT, Stroop and WAIS part IV Digit Span scores

to assess the MLE on cognitive functioning

Toelichting onderzoek

Achtergrond van het onderzoek

Background an rationale:
Deep brain stimulation (DBS) of the subthalamic nucleus (STN) is an effective treatment for advanced Parkinson's disease (PD). In the first days to weeks after surgery, alleviation of PD symptoms without active stimulation is often observed, referred to as the microlesion effect (MLE). The presence of MLE on cognition after DBS surgery has not been studied well, while this non-motor aspect of PD might be of great importance to the patient.

Objective:
To determine the presence and predictive value of MLE on cognition after DBS in PD.

Study design:
Prospective observational study.

Study population:
Adult PD-patients undergoing DBS of the STN.

Main study parameters/endpoints:
The primary endpoints of the study are the SDMT, Stroop and WAIS part IV Digit Span scores to assess the MLE on cognitive functioning.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
There are no risks associated with the proposed study.
Assessing cognitive functioning 12 months after DBS surgery leads to better attention for possible cognitive deficits, which could initiate early postoperative cognitive deterioration detection and cognitive training to prevent further cognitive deterioration.

Doel van het onderzoek

The hypothesis is that the microlesion effect affects cognitive functioning in Parkinson's disease patients undergoing STN-DBS.

Onderzoeksopzet

Various clinical tests will be administered on several time points:
1 day before the surgery: the MoCA
The morning before the surgery: SDMT, Stroop, WAIS IV Digit Span
During the surgery, after electrode insertion: SDMT, Stroop, WAIS IV Digit Span

2 days after the surgery: SDMT, Stroop, WAIS IV Digit Span
12 months after the surgery: the MoCA

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Adult that are selected for DBS in the STN by the multidisciplinary working group
- Oral- and written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Unstable internal or other pathologies
- Not able to apprehend the consequences of surgical intervention
- Depression or other psychiatric instabilities
- Dementia (Mattis Dementia Rating Scale (DRS) <120 or Scales for Outcomes of Parkinson’s disease-cognition (SCOPA-Cog) <20)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8319
Ander register	METC UMCG : METc2020/133

Resultaten