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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25026

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Parkinson's disease

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The MoCA score on the day before the surgery and at 6 months, to assess the predictive value of perioperative cognitive functioning (MoCA scores are correlated to SDMT, Stroop and WAIS part IV Digit Span scores to assess this topic).

Study description

Background summary

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.

Study objective

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

Study design

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

Contacts

Public
University Medical Center Groningen
Naomi Kremer

+31 652174838
Scientific
University Medical Center Groningen
Naomi Kremer

+31 652174838

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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	NL8319
Other	METC UMCG : METc2020/133

Study results