The microlesion effect on cognition after Deep Brain Stimulation in Parkinson's disease

Published: 20-05-2020
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To determine the presence and predictive value of MLE on cognition after DBS in PD.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON49024

Source
ToetsingOnline

Brief title
Microlesion effect on cognition after DBS

Condition

- Movement disorders (incl parkinsonism)
- Nervous system, skull and spine therapeutic procedures

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DBS, Neuromodulation, Neurosurgery, Parkinson

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 12 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

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.

Study objective

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

Study design

Prospective observational study

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adults (over the age of 18 years) that are selected for DBS in the STN by the multidisciplinary working group
Oral- and written informed consent

Exclusion criteria

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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-11-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	20-05-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-12-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL72672.042.20
Other	NTR NL8319