MEG in Parkinson¡¯s disease patients with DBS

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19892

Source
NTR

Health condition

Parkinson's disease, Deep Brain Stimulation

Sponsors and support

Primary sponsor: VU medical center
Source(s) of monetary or material Support: Direct funding by University
Amsterdam Neuroscience

Intervention

Outcome measures

Primary outcome

Stimulation site-specific neurophysiological measures, as obtained by MEG recordings, and differences in the exact locations and structural connections of each contact point, as obtained by brain imaging.

-Correlation of neurophysiological- and structural data to clinical measures of non-motor symptoms (both pre- and post-DBS), obtained in the context of standard clinical care and clinical studies.

Secondary outcome

MDS-UPDRS III-ratings are scored on a regular basis as part of clinical care and can be correlated to the functional and structural networks as well.

Study description

Background summary

Deep brain stimulation (DBS) of the subthalamic nucleus (STN) is an effective surgical intervention for motor symptoms in Parkinson’s disease (PD), but it can induce negative cognitive and psychiatric side effects in up to 25% of patients. Usually the electrodes targeted at the STN are implanted bilaterally. Each electrode may have four or eight contact points. Clinical improvement and side effects differ per stimulated contact point, but the cause of these effects is only partly understood. At present, it may take months to identify the optimal DBS settings via trial and error. Stimulation of white matter tracts surrounding the STN is considered important for the clinical effects of DBS. The relationship between contact points and white matter tracts, hence the stimulation sites, can be approximated using diffusion tensor imaging (DTI). Magnetoencephalography (MEG, a recording of magnetic fields related to brain activity) can be used to characterize stimulation site dependent functional networks that can be associated with the occurrence of (side) effects. The combination of contact point-specific functional and structural brain network characteristics can help to identify stimulation sites prone to induce side effects. This could improve clinical outcome by aiding DBS electrode placement and contact point selection.

Objectives are: a) Identification of stimulation site-specific functional and structural brain network characteristics in patients with PD and STN-DBS.

b) Relating subject-specific stimulation sites and functional network changes to measures of cognitive and psychiatric side effects.

Study design: This explorative study is an observational, cross-sectional study using MEG to characterize stimulation site-specific functional brain network characteristics. The functional networks will be obtained by alternatingly stimulating individual stimulation sites. This will be combined with clinical data from the Academic Medical Center (AMC) Amsterdam, where patients have undergone STN DBS. In the context of standard clinical care, pre- and post-DBS neuroimaging and evaluation of cognitive side effects will be conducted. Pre-DBS assessment of psychiatric symptoms takes place in the context of standard clinical care as well, whereas post-DBS information on psychiatric side effects will be obtained using questionnaires in anticipation of- and during the study visit for MEG recordings at VUmc.

Study objective

DBS-related cognitive decline and psychiatric side-effects in Parkinson's disease (PD) patients

can be studied from a functional- and structural network point of view. We will characterize functional and structural brain networks in PD patients treated with DBS and correlate this with DBS-related non-motor side effects. We expect that the knowledge obtained in this study can improve electrode positioning and contact point selection.

Study design

One study visit in which MEG-measurements and questionnaires on psychiatric symptoms take place.

Intervention

In each subject, eleven MEG recordings of 5 minutes duration will be completed in a single session. The first MEG recording will be performed in the optimal DBS settings of the participant. After this, nine MEG recordings will take place using different DBS settings in a randomized order: during eight recordings in turn unilateral stimulation of each of the individual contact points takes place and one recording will be performed in the DBS-OFF state.

Contacts

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Eligibility criteria

Inclusion criteria

-Having undergone STN-DBS placement for PD six months or longer before MEG registrations;
-Age ¡Ý 18 years;

-Monopolar stimulation

-Pre-operative DTI data available and of sufficient quality.

-Post-operative NPO is available and was performed in the same DBS settings as during the MEG recordings.

Exclusion criteria

-Hoehn and Yahr stage higher than 3, as determined in the DBS ON- (but medication OFF-)state.

-Anatomical deformities that prevent the subject from undergoing an MEG registration in supine position (i.e. thoracic kyphosis);

-Continuous intrajejunal levodopa or subcutaneous apomorphine infusion in addition to DBS;

-Dementia according to the Movement Disorder Society criteria for PD with dementia.

-Conditions that will cause excessive MEG artefacts (other than the DBS electrode and stimulator).

-A history of stroke or major vascular lesions on brain MRI;

-A history of major traumatic brain injury;

-Peri-operative intracerebral complications (e.g. bleeding or infection) related to STN-DBS placement inflicting permanent changes;

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2017
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-08-2017
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	NL6431
NTR-old	NTR6607
Other	METC van het VUmc : 2017-306

Study results