MEG in Parkinson¡¯s disease patients with DBS

Gepubliceerd: 09-08-2017 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19892

Bron
NTR

Aandoening

Parkinson's disease, Deep Brain Stimulation

Ondersteuning

Primaire sponsor: VU medical center
Overige ondersteuning: Direct funding by University
Amsterdam Neuroscience

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

VU University Medical Center, Amsterdam

H.W. Berendse
Department of Neurology

Amsterdam
The Netherlands
+31 204442830

Wetenschappelijk

VU University Medical Center, Amsterdam

H.W. Berendse
Department of Neurology

Amsterdam
The Netherlands
+31 204442830

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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;

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2017
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-08-2017
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	NL6431

Register	ID
NTR-old	NTR6607
Ander register	METC van het VUmc : 2017-306

Resultaten