Visualising subdivisions of the Subthalamic Nucleus in Parkinson*s Disease with Ultra-High Field MRI

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

Summary

ID

NL-OMON45690

Source
ToetsingOnline

Brief title
PD STN connectivity UHF

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's, Parkinson's Disease, PD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Parkinson's Disease, Subdivisions, Subthalamic Nucleus, Ultra-High Field MRI

Outcome measures

Primary outcome

To create individualised, subject-specific connectivity profiles of STN structure and function by combining DWI and rs-fMRI data; specifically, to identify exclusive motor components of the STN.

Secondary outcome

To assess the quality differences across 3T and 7T MRI

To create anatomical atlases of the STN. These atlases aim to identify the extent of individual variability, both in healthy brains and in PD. These atlases will be created by combining individual manually segmented STNs from 7T structural MRI.

To develop a prognostic model that can be used to determine whether PD patients are suitable candidates for DBS. The prognostic model will be based on STN anatomy (e.g. location and size), connectivity (structural and function), pre-operative UPDRS scores, resultant DBS electrode placement and clinical outcome.

Study description

Background summary

See introduction section of the METC (pages 9-14).

Study objective

The current study aims to go further than the previous METC application of B. Plantinga (2014). In addition to providing optimized structural delineations of the STN via the increased contrast offered by 7T MRI, the existence of structural subdivisions within the STN will be assessed using

UHF DWI with additional resting-state functional MRI (rs-fMRI). It is likely that STN subdivisions are better delineated based on both domain specific, functional networks as well as direct, structural white matter tract connections.

The combination of data from DWI and rs-fMRI images will allow for the creation of individualised connectivity profiles for both PD patients and healthy controls.

For PD patients, the resultant connectivity profiles may offer a selection of potential coordinates that may be used as electrode targets for DBS surgeries.

Quantifying the structural and functional nature of the STN as well as surgical outcomes may aid the development of a prognostic model which can be used to better select suitable PD candidates for DBS in the future.

Additionally, STN segmentations will be used to create anatomical atlases in both the healthy and diseased brain. Such atlases are essential for both scientific research and for localization procedures in neurosurgery; particularly in relation to acknowledging the extent of individual differences in neuroanatomy.

Study design

observational cohort

Study burden and risks

All subjects, both patients and healthy, will be assessed in terms of their suitability to participate in the research.

Only suitable subjects will be included for scanning. The burden for the subjects, and in particular, the patients, rests with extended scanning time of up to 60 minutes, which is substantially more than is currently required for the standard medical procedures. However, a previous METC accepted study has proved this is necessary to obtain optimal images and can produce valuable information that cannot be obtained with the currently utilized clinical

techniques. Subjects will be given the choice of splitting the scan in to two 30 minute sessions. Scanning will in no way interfere with clinical treatment. When attention is paid to the contra-indications for MRI, 7T MRI is harmless. Patients may benefit from individualised and optimised treatment during this study or in the future, as will other PD patients not included in the study. There is no direct benefit of the healthy controls, other than knowing that they will contribute to research regarding the structure and function of the STN.

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

Inclusion criteria for Parkinson's patients ;1. Patients must be mentally competent (Wilsbekwaam).;2. Patients must meet all requirements of the standard Scannexus screening

form (see METC appendix).;3. Patients much be aged between 18 and 80 years old.;Inclusion criteria for Healthy Volunteers ;1. Healthy controls must be mentally competent (Wilsbekwaam).;2. Healthy controls must not be suffering from any neurological or psychiatric illnesses.;3. Healthy controls must meet all requirements of the standard Scannexus screening form (see METC appendix).;4. The age and gender of healthy control subjects should not significantly differ to the age and gender of the PD patients. ;5. Subjects must be aged between 18 and 80 years old.

Exclusion criteria

1. Former severe head injury requiring surgery.;2. Stroke.;3. Suffering from any other non-psychiatric brain diseases. ;4. Metallic prostheses or pacemaker in the subject*s body or other contra indications for MRI. Prior to scanning, subjects will fill out a screening form (see METC appendix). This form will be sent with the information letter to all subjects. An additional form will be filled out on the day of the scan. Both are to ensure any contra indications are known to both the subject and the scanning technician.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	07-08-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL60342.068.17