Atlasing the human subcortex of a Parkinson's disease population

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To develop and validate a probabilistic subcortical atlas of a PD population using 7Tesla MRI, and to validate this atlas for use on 3T MRI data.

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

Summary

ID

NL-OMON47807

Source
ToetsingOnline

Brief title
Subcortex

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: NWO/STW project Atlasing the human subcortex;toegekend aan Prof dr Forstmann;PI

Intervention

Keyword: 7 Tesla, MRI, Parkinson's disease, Subcortical brain structures

Outcome measures

Primary outcome

Obtained MRI data will be used to develop a probabilistic subcortical 7T atlas of a PD population. We will measure signal to noise ratio, Dice coefficients, Center of Gravity measurements, susceptibility values, and connectivity in multiple subcortical brain structures. To validate and quantify the advantage of using 7T over 3T scans, we will compare 7T and 3T results in the first year.

Secondary outcome

N.A.

Study description

Background summary

With the advent of ultra-high field (UHF) 7Tesla MRI imaging small structures located deep in the brain can now for the first time be visualized providing a high level of anatomical detail. In view of the increasing application of deep brain stimulation (DBS) surgery targeting subcortical brain nuclei in Parkinson*s Disease (PD) patients, it is now possible to develop a clinical atlas of the human subcortex using ultra-high resolution MRI. In this study we intend to collect and analyse MRI images from patients with PD that allow the development of this atlas. To this end we will perform a prospective cohort study in which we will obtain structural and resting state MR images using UHF scans, as well as 3T MR images for clinical validation of the use of 7T MRI. The atlas will be of significant value for application by neurosurgical centres worldwide that do not have access to UHF MRI systems.

Study objective

To develop and validate a probabilistic subcortical atlas of a PD population using 7Tesla MRI, and to validate this atlas for use on 3T MRI data.

Study design

Prospective cohort study

Study burden and risks

Participants will be contacted to assess their suitability to participate in MRI research. Participants who meet the inclusion and none of the exclusion criteria will be invited to the Spinoza Centre for neuroimaging. Their eligibility to participate in MRI research will be confirmed and they will undergo 7T MRI scanning. MRI is a safe non-invasive imaging procedure, which does not use ionizing radiation and has low inherent risks. Ultra-high resolution (7T) imaging has been applied to PD patients before and has proven to be valuable in PD research. Participants will undergo additional 3T MRI scanning. No serious adverse effects have been reported for 3T or 7T MRI scanning.
For all participants, scans will be acquired during one 7T scan session of approximately 60 minutes. In the first year, an additional 3T scan session of approximately 45 minutes will be obtained. Scanning will in no way interfere with clinical treatment and will result in minor discomfort for the patients.

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

Age between 18 and 80 years old
Clinical diagnosis of Parkinson's disease based on self-reporting by the patient
Patients must be able to walk into the scanner room and climb onto the scanner bed
Current treatment with anti-Parkinson medication
Patients must meet the requirements to safely undergo MRI scanning, as determined using an MR-checklist, and a short interview
Signed informed consent

Exclusion criteria

A history of concomitant psychiatric or neurological disease, other than Parksinson's disease as well as a history of stroke or traumatic brain injury, as assessed by self reports
Claustrophobia
Implanted ferromagnetic particles
Any contra-indication for MRI research, as assessed by an MRI-checklist

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL61200.018.17