The role of imaging in Parkinson*s disease subtypes: a pilot study .

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The primary objective of this study is to detect statistically significant differences between the most severely affected PD subtype and controls on 3T imaging parameters.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational invasive

Summary

ID

NL-OMON35081

Source
ToetsingOnline

Brief title
Imaging in Parkinson*s disease subtypes.

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Internationaal Parkinson Fonds

Intervention

Keyword: Imaging, Parkinson's disease, Subtypes

Outcome measures

Primary outcome

The main study parameters of this study will include clinical and magnetic resonance imaging (MRI) parameters. Clinical data include important demographic and disease-related characteristics as well as measures for disease severity, and the important motor (motor functioning and motor complications) and non-motor domains (cognition, depression, psychotic symptoms, depression, sleep problems, and autonomic dysfunction). The combination of clinical scores allocates patients in one of the four subtypes, and in this study, only patients allocated in the most severe PD subtype 4 are participating. The MRI measures will include volumetric, diffusion, and functional MRI.

Secondary outcome

Not applicable.

Study description

Background summary

The clinical heterogeneity among patients with Parkinson*s disease (PD) reflects the existence of subtypes. Recently, four distinct subtypes which differ with respect to the severity of a complex of predominantly non-dopaminergic features and motor complications were identified in PD patients with longstanding disease. At disease onset, these clinical characteristics unfortunately are not an important feature of the phenotype and thus are of no or limited use in predicting subtypes. Quantitative biomarkers of the characteristics which discriminate the existing subtypes may have the potential to identify subtypes before overt expression of the disorder. With regard to the field of imaging, not much is known about potential biomarkers possibly relevant in the discrimination of PD subtypes. In order to evaluate if 3 Tesla MRI can provide potential biomarkers for the discrimination of subtypes in PD, a first step in the process of biomarker development is to evaluate if patients within the most severely affected PD subtype significantly differ with

regard to the outcome measure of the potential biomarker from control subjects.

Study objective

The primary objective of this study is to detect statistically significant differences between the most severely affected PD subtype and controls on 3T imaging parameters.

Study design

The proposed study will be a cross-sectional case-control study.

Study burden and risks

PD is a progressive disorder with an unknown cause, with only symptomatic treatment options. This study asks some effort from the patients and is not directly helping the individual, but will provide more insight in the usefulness of imaging in PD research. The duration of all measurements may lead to fatigue in some patients; in such cases, rest periods will be offered. If patients develop more severe symptoms due to the measurements as performed in the study, the study will be adapted to the person*s wishes, or will be ended. If necessary, the neurologist on duty will be consulted.

Anatomical scans will be examined by a physician for unexpected findings. In case of an unexpected finding a neurologist will be consulted and the case will be discussed. If necessary, the participant*s general practitioner (GP) will be contacted within 3 weeks after the scan. The participant will receive notice that the GP was contacted; the GP will inform the participant about the findings.

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

PD patients must fulfill the United Kingdom Parkinson*s Disease Society Brain Bank criteria for idiopathic PD.
PD patients must be allocated to subtype 4 based on their clinical scores.
A minimum age of 18 years is required for both patients and control subjects.

Exclusion criteria

Control subjects with a disease of the central nervous system.
Participants with a contraindication for MRI.

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-04-2010
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-06-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL31831.058.10