Biomarkers for differentiation of Parkinson*s disease subtypes.

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The main objective of this study is to detect potential biomarkers for the differentiation of PD and DLB and the differentiation of PD subtypes by using neuroimaging.

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

Summary

ID

NL-OMON39292

Source
ToetsingOnline

Brief title
Biomarkers for 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: collectebusfondsen

Intervention

Keyword: Biomarkers, Imaging, Parkinson's disease, Subtypes

Outcome measures

Primary outcome

The main study parameters of this study will include magnetic resonance imaging (MRI) parameters, and clinical measures. 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, sleep problems, and autonomic dysfunction). The combination of clinical scores will allocate PD patients in one of the four subtypes. MRI will be carried out on a 3T scanner and will include volumetric, diffusion, and functional MRI parameters.

Secondary outcome

Not applicable.

Study description

Background summary

In prevalent Parkinson*s disease (PD), subtypes can be identified by clinical characteristics. Identification of PD subtypes may have important consequences for both the development of tailored treatment strategies and research of underlying mechanisms since homeogeneous patient groups contribute to a better coherence between phenotype, pathophysiology and genotype. In early PD, however, clinical characteristics are insufficient to identify subtypes. In addition, in the early phase, it is difficult to distinguish dementia with Lewy bodies (DLB) from PD. Early differentiation of DLB and PD and differentiation of clinical subtypes of PD might be possible with the use of quantitative biomarkers of clinical traits. An important step in the development of biomarkers that are potentially useful in early PD and DLB, is the identification of biomarkers in established clinical subtypes of prevalent PD and in prevalent DLB patients. In this study, neuroimaging will be used to

identify quantitative biomarkers in prevalent PD subtypes and in prevalent DLB.

Study objective

The main objective of this study is to detect potential biomarkers for the differentiation of PD and DLB and the differentiation of PD subtypes by using neuroimaging.

Study design

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

Study burden and risks

PD and DLB are progressive disorders 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 pathophysiology of PD and DLB. 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

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

For all participants a minimum age of 18 years is required.
All PD patients must fulfill the United Kingdom Parkinson*s Disease Society Brain Bank criteria for idiopathic PD. Patients with Lewy body dementie (DLB) must fulfill the McKeith DLB criteria and all patients must be diagnosed with PD or DLB by a movement disorder specialist.
Only patients who are mental competent are included.

Exclusion criteria

Participants with a contraindication for MRI are excluded.
Patients who underwent stereotactic surgery were excluded.
Controls with a disease of the central nervous system are excluded.

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:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	17-01-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	04-09-2013
Application type:	Amendment
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	NL34590.058.10