Molecular profiling of Parkinson's disease

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The main objective of this study is to develop a method to identify susceptible pathways of redox metabolism and bioenergetics in peripheral blood cells and induced pluripotent stem cells from patients with PD and DLB.

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

Summary

ID

NL-OMON39947

Source
ToetsingOnline

Brief title
Molecular profiling of Parkinson's disease

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: Bioenergetics, Parkinson's disease, Progression, Redox metabolism

Outcome measures

Primary outcome

The main parameters of this study are the redox responses to pro-oxidant challenge tests and bioenergetics functions such as mitochondrial respiration and glycolytic activity. All patient groups will be characterized on environmental exposures (smoking, insecticides, herbicides). For redox susceptibility profiling, 20 ml blood will be drawn via venapuncture and a skin biopsy will be performed. Differences in redox response to toxin challenge will be determined in peripheral blood cells and induced pluripotent stem cells by differential labelling of reduced and oxidized cysteines residues with maleimide technology followed by Fluorescence Assisted Cell Sorting (FACS) analysis.

Secondary outcome

Clinical assessments will be used to assess the progression of the core features of PD, which is necessary to allocate patients to one of the subgroups. The patients with DLB will be assessed clinically to be able to compare the clinical function of PD and DLB patients.

Study description

Background summary

Different processes fundamental to neuronal vitality, including the maintenance of protein homeostasis, oxidative stress and bioenergetics play a role in the pathobiology of Parkinson*s disease (PD). Inter-individual differences in the extent to which these processes are affected likely account for the existence of differences in disease course and progression between PD patients. In this study, we will focus on disturbances of redox metabolism and bioenergetics as a

potential pathobiological mechanism of PD and dementia with Lewy Bodies (DLB), and their role in the expression of differences in progression between patients.

Study objective

The main objective of this study is to develop a method to identify susceptible pathways of redox metabolism and bioenergetics in peripheral blood cells and induced pluripotent stem cells from patients with PD and DLB.

Study design

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

Study burden and risks

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 clinical assessments and venapunctures are routinely performed at our outpatient clinic and are well tolerated by PD patients. If patients develop fatigue, the assessment is adapted to the person*s wishes, or will be ended.

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

For all participants a minimum age of 18 years is required.
All patients with Parkinson's Disease (PD) must fulfill the United Kingdom Parkinson's Disease Society Brain Bank criteria for idiopathic PD. Patients with Dementia with Lewy Bodies (DLB) must fulfill the McKeith DLB criteria and all patients must be diagnosed with PD or DLB by a movement disorder specialist.
All participants must be able to give informed consent.
Buffy coats of controls are included if they have no diseases of the central nervous system or conditions associated with the immune system.

Exclusion criteria

Participants should have no inflammatory diseases.
Participants are excluded when anti-inflammatory drugs (NSAIDs, corticosteroids), immunosuppressive medication or anti-oxidants (Vitamin C) are used.
Participants are excluded when having an infectious disease at the time of the measurements.
Participants who currently smoke are excluded.
Patients who underwent stereotactic surgery 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:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-02-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	13-11-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	02-08-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL41867.058.12