Linking protein profiles to disease progression and clinical expression in Parkinson*s disease: part two, longitudinal outcomes

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The main objective of this study is to predict the rate of decline for both motor and cognitive function in an existing PD patient cohort using a combination of baseline CSF and blood biomarker profiles (T0). The secondary objective is to determine...

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

Summary

ID

NL-OMON47594

Source
ToetsingOnline

Brief title
PROGRESS-PD

Condition

- Movement disorders (incl parkinsonism)
- Dementia and amnestic conditions

Synonym
Parkinson, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: biochemical biomarkers, cognitive decline, motor progression, Parkinson's disease

Outcome measures

Primary outcome

* UPDRS III score (T1-T0)

* MMSE score (T1-T0)

Secondary outcome

* Hoehn and Yahr stage (T1)

* Test scores representing the five most affected cognitive domains in PD

(attention, executive function, memory, visuospatial function and language)

(T1)

* Presence of PD mild cognitive impairment (PD-MCI) and PD dementia (PD-D)

according to the MDS diagnostic criteria (T1)

* Activity of Daily Living (T1): UPDRS part II, Schwab and England ADL scale

* CSF and blood-based biomarker concentration (T1)

* Predefined genetic factors associated with cognitive decline in PD

* Test scores for neuropsychiatric symptoms in PD (T1): SCOPA

Psychiatrische Complicaties (SCOPA-PC), Beck Depression Inventory, Beck Anxiety

Inventory

Study description

Background summary

Parkinson*s disease (PD) is a neurodegenerative disorder characterized by progressive decline involving a broad range of functional domains. There is considerable variability in the rate of progression of motor manifestations and in the prevalence of non-motor manifestations. Unfortunately, prediction of the differences in clinical expression is difficult and currently there is no effective biomarker to robustly predict or monitor disease progression in PD.

Study objective

The main objective of this study is to predict the rate of decline for both motor and cognitive function in an existing PD patient cohort using a combination of baseline CSF and blood biomarker profiles (T0). The secondary objective is to determine whether changes in the level of CSF and/or blood-based biomarkers over time correlate with clinical measures of motor progression, cognitive decline, neuropsychiatric symptoms and Activities of Daily Living (ADL) functions (T1 versus T0).

Study design

longitudinal cohort study

Study burden and risks

For patients still under treatment in the VU university medical centre, study procedures will be combined with a regular visit to the outpatient clinic for movement disorders. For patients under treatment in other clinics, study procedures will be performed during a single visit to the outpatient clinic. Clinical examination, cognitive testing and filling out questionnaires will take approximately four hours, depending on the functional state of the participating patients, including 60 minutes for breaks. Lumbar puncture and venous blood puncture will take approximately 30 minutes; a total amount of 12 ml CSF and 25 ml blood will be obtained from each patient. Risks associated with a venous blood puncture include a local haematoma and, rarely, an infection. Risks associated with a lumbar puncture include post lumbar puncture headache, infection (arachnoiditis, meningitis or abscess) and haemorrhage. These risks will be minimized by the applied puncture procedures and experienced physicians/nurses. As the main objective of this project is prediction of the rate of cognitive decline, it is inevitable that some patients will have developed cognitive impairment at follow-up (8-9 years after baseline) and/or are diagnosed with dementia. Therefore, this study cannot be conducted without the participation of subjects suffering from cognitive

deficits.

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

* Patients from the baseline cohort diagnosed with Parkinson*s disease according to the MDS Clinical Diagnostic Criteria for Parkinson*s Disease
* Mini-Mental State Examination (MMSE) score *18 at recruitment
* Being able to understand the aim of the study and the study procedure and give written informed consent

Exclusion criteria

* A history of neurological disorders other than PD, that affect the central nervous system or are known to influence CSF proteins
* Unwillingness to be informed of unexpected medical findings;Potential subjects are eligible to participate in this study if they cannot undergo lumbar puncture due to the following reasons:
* No CSF collected at baseline
* Use of anticoagulants or a history of coagulation disorders
* Infected skin over the needle entry site for lumbar puncture
* Signs of raised intracranial pressure
* Travelling to the VUmc outpatient clinic is too burdensome
* Unwillingness to undergo lumbar puncture
These subjects we will undergo all study procedures with the exception of CSF collection.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	20-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	26-04-2018
Application type:	Amendment
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	NL60345.029.17