Profiling Parkinson's disease

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Primary objective: To evaluate the role of existing and novel quantitative biomarkers in understanding the heterogeneity in the Parkinson*s phenotype (i.e. rate of progression, cognitive and neuropsychiatric impairment and motor dysfunction) and...

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

Summary

ID

NL-OMON54513

Source
ToetsingOnline

Brief title
ProPark

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw,AbbVie B.V.,bedrijven,Centre for Human Drug Research,Hoffmann-La Roche,Lundbeck,PHARMO Institute NV

Intervention

Keyword: biomarkers, cohort, parkinson's disease, personalised medicine

Outcome measures

Primary outcome

main study parameters are biomarker concentrations (i.e. blood, CSF & feces),

skin alpha-synuclein (α-syn) aggregation, ADR occurrence and cognition scores.

Secondary outcome

nvt

Study description

Background summary

Pharmacologic treatment of Parkinson*s disease (PD) is mainly aiming to alleviate motor or neuropsychiatric symptoms and does not alter disease progression. Treatment follows a *one-size-fits-all* approach and does not consider genetic factors underlying between-patient differences in treatment response and susceptibility to adverse drug reactions (ADRs).

Study objective

Primary objective: To evaluate the role of existing and novel quantitative biomarkers in understanding the heterogeneity in the Parkinson*s phenotype (i.e. rate of progression, cognitive and neuropsychiatric impairment and motor dysfunction) and predicting treatment response as well as the occurrence of ADRs over a three-year period.
Secondary Objective: To develop a biobank containing comprehensive and uniformly acquired longitudinal clinical data and biological samples for identification and validation of biomarker panels and data-driven approaches to unravel heterogeneity in the Parkinson*s phenotype (i.e. rate of progression, cognitive and neuropsychiatric impairment and motor dysfunction), treatment response and occurrence of ADRs.

Study design

longitudinal cohort study

Study burden and risks

Participants are invited to come to the study site in Leiden (LUMC), Amsterdam

(AMC/VU), Rotterdam (Erasmus), Utrecht/Woerden (Antonius) or Amersfoort (Meander) for 2-3,5 hours of data collection four times during the 3-year study duration and coupled to this visit perform an at home assessment (i.e. questionnaires (115-160 minutes), phone interview (10-50min) and wearables (1 week) and optionally a smartphone application (1 week)). Controls will be assessed twice. All study assessments are routine exams done in standard clinical practice and are generally well tolerated. Blood, feces (all visits), CSF (only at first and third visit in 100 patients and 50 controls only), MRI (only at first visit in 100 patients) and skin biopsies (only at first and third visit in 400 patients and 100 controls only) will be collected. Blood draws, lumbar punctures and skin biopsies come with a small discomfort. Risks associated with venous blood punctures, lumbar punctures and skin biopsies include a local hematoma and, rarely, an infection. These risks will be minimized by the applied puncture procedures carried out by experienced physicians/nurses.
Wrist and back sensors will be worn daily for up to 24 hours, once a year for a one-week period each in patients and twice in controls. These small, unobtrusive electronic devices are easily applied and poses no significant safety issues. During this week, participant will perform daily active tests of max. 30 min a day. In addition they will fill-in daily questionnaires with a duration of max. 5 min a day. Optionally, a smartphone application will be used to passively collect data and 1 additional test is added to the daily active tests.

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

Prior to enrollment in this clinical investigation, candidates must meet ALL of the following criteria:
Patients:
• recently diagnosed with PD (N=625; time since Parkinson diagnosis <= 2 years) or not recently diagnosed with PD (N=625; time since Parkinson diagnosis >2 & <=15 years) (Time since Parkinson diagnosis (in years) made by a neurologist; In order to obtain a good representation of the PD population an even distribution with respect to gender and age (age categories: <55 years, 55-65 years and >65 years) in both patient groups, will be attempted.
• 18 years or older;
• able to read and speak Dutch
• Providing IRB-approved Informed Consent;
• Willing, competent and able to comply with all aspects of the protocol, including follow-up schedule and biospecimen collections.

Controls:
• 18 years or older
• Healthy (Self-report)
• Is able to read and speak Dutch
• Even distribution with respect to gender and age of the patient groups will be attempted
• Providing IRB-approved Informed Consent;
• Willing, competent and able to comply with all aspects of the protocol, including follow-up schedule and biospecimen collections.

Exclusion criteria

Patients
• Patients who received brain surgery for Parkinson*s disease, patients who currently use levodopa continuous intestinal gel or patients who are currently receiving apomorphine treatment.

• presence of co-morbidities that would hamper interpretation of parkinsonian disability, in the opinion of the Investigator.
• MoCa score of <=16 (indicates dementia)
• Unwillingness to be informed of unexpected medical findings

Controls
• A history of neurological disorders that affect the brain or central nervous system
• Abnormal findings at general neurological examination
• Unwillingness to be informed of unexpected medical findings

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):	29-07-2021
Enrollment:	1515
Type:	Actual

Ethics review

Approved WMO

Date:	15-04-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	14-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-09-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-03-2025
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	NL70698.029.19
Other	NL9788