Diagnostic accuracy of novel blood-biomarkers for Parkinson's disease

Published: 14-03-2024
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Collecting blood samples of healthy volunteers (n=650) which can serve as a reference for the Personalized Parkinson Project.

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

Summary

ID

NL-OMON56654

Source
ToetsingOnline

Brief title
Diagnostic biomarkers for Parkinson's disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO ZonMW

Intervention

Keyword: Biobank, Biomarkers, Parkinson

Outcome measures

Primary outcome

Minimal clinical data extracted from questionnaires and storage of patient

material (cells, serum, plasma, DNA, RNA).

Secondary outcome

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Study description

Background summary

Current biomarkers for Parkinson*s disease are especially valuable for the differential diagnostics but not for the prediction of the widely varying differences between patients in prognosis, rate of progression, time to development of important milestones, or treatment response. The Personalized Parkinson Project (NL59694.091.16) aims to develop new biomarkers to fill this gap, but the cohort does not include healthy controls without Parkinson*s, which hampers the investigation of blood-based biomarkers.

Study objective

Collecting blood samples of healthy volunteers (n=650) which can serve as a reference for the Personalized Parkinson Project.

Study design

Prospective biobanking program with registry of minimal clinical data and structured blood sampling at inclusion. Samples will be collected to isolate cells, plasma, serum, RNA and DNA. Data will be stored in a Castor EDC database. Blood will be stored in the Radboud UMC biobank.

Study burden and risks

The risk and burden for the biobank participants is negligible (one visit with blood draw). The venepuncture is associated with a small risk for local hematoma. There*s no benefit for participants. The biobank can be used to develop new biomarkers for Parkinson*s disease.

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

- Subject is an adult, at least 18 years of age.
- Subject can read and understand Dutch.
- Subject has completed CMO-approved Informed Consent.
- Subject is willing, competent, and able to comply with all aspects of the protocol, including biospecimen collections.

Exclusion criteria

- Subject is pregnant or breastfeeding.
- Subject has Parkinson*s disease.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-10-2024
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	14-03-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-07-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL85147.091.23