

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Movement disorders (incl parkinsonism)
<b>Study type</b>	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