# Blood samples for pre-analytical variable testing

Published: 24-07-2019
Last updated: 09-04-2024

To validate analytical parameters of blood-based biomarker methods and assess the influence of pre-analytical blood handling on levels of those biomarkers.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Neurological disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON55496

**Source**
ToetsingOnline

**Brief title**
Blood samples for pre-analytical variable testing

### Condition

- Neurological disorders NEC

**Synonym**
Neurological diseases

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** divers (2005190 - Project Alzheimer bloed biomarkers)

## Intervention

**Keyword:** Biomarker, Blood, Stability of proteins, Technical validation

## Outcome measures

### Primary outcome

Blood material will be processed immediately after collection to create sample sets. Each sample set will be handled differently according to a strict pre-defined experimental set-ups. These sample sets can then be used to study technical parameters of laboratory methods and to study stability of specific proteins upon different pre-analytical sample handling procedures. Study endpoint is the qualification of laboratory methods and the decision for an optimal pre-analytical sample handling protocol per potential biomarker of interest.

### Secondary outcome

not applicable

# Study description

### Background summary

In the Neurochemistry laboratory of the Amsterdam UMC, location VUmc, work continuously focusses on identifying new biomarkers, and developing and qualifying methods to quantify those new biomarkers. When determining if a potential biomarker relates to disease status, also technical validation experiments have to take place. New laboratory methods have to be validated by screening for quality, accuracy, precision and robustness. Additionally, stability of the protein of interest in blood upon pre-analytical sample handling procedures has to be carefully validated. Pre-analytical sample handling covers the complete process from blood collection in the optimal tube type, the conditions of tube centrifugation, the process of dividing the sample in smaller aliquot tubes, the freezer storage conditions and (multiple times) thawing of samples for biomarkers. The Neurochemistry lab already showed the

importance of pre-analytical sample handling standardization in CSF. These technical and pre-analytical validation aspects of biomarker discovery research should also be done in blood, therefore fresh blood material is required.

### Study objective

To validate analytical parameters of blood-based biomarker methods and assess the influence of pre-analytical blood handling on levels of those biomarkers.

### Study design

Adults (> 18 years of age) who present at the department of Clinical Chemistry (VUmc) for any diagnostic blood collection or who present at the Alzheimer center Amsterdam where they donate blood for storage in the Amsterdam Dementia Biobank will be asked for consent to participate in this study. Following their venipuncture, additional blood will be collected. Total volume of the combined collection for diagnostics/biobanking and our study will never exceed 70 milliliters.

### Study burden and risks

There will be no significant burden or additional risk to the volunteers. The volunteer will donate additional blood via the venipuncture that is already performed for the diagnostic/biobanking blood collection. There are no extra visits necessary. Total volume of the combined collection for diagnostics/biobanking and our study will never exceed 70 milliliters. There are no personal benefits of participation for the volunteer.

## Contacts

**Public**
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
**Scientific**
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

Adults aged > 18 years.

## Exclusion criteria

Non-adults aged < 18 years.

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 14-10-2019 |
| Enrollment: | 375 |
| Type: | Actual |

# Ethics review

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|---|---|
| Approved WMO Date: | 24-07-2019 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 17-11-2020 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 19-08-2021 |
| 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 | NL69123.029.19 |