Early variations of immune aging: the EVIA-NL study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56850

Source
ToetsingOnline

Brief title
EVIA-NL

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Immune disorders NEC

Synonym
Aging; Immunoaging; Inflammaging

Health condition

systemische veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: spinozapremie prof. Mihai Netea

Intervention

Keyword: Aging, Healthspan, Immunology, Inflammation

Outcome measures

Primary outcome

We refer to the protocol, sections 2 and 5

Secondary outcome

N/A

Study description

Background summary

Despite an increase in lifespan over the last decades, our healthspan lags behind. In our aging population, t is pressing that we prevent age-related morbidities and associated burden on the health care system. Instead of investigating aging in already aged populations, the currently proposed study aims to elucidate the process of immune aging in relation to biological aging, demographic and lifestyle factors and to identify early biomarkers and pathways associated with fast versus slow immune aging and aging endotypes.

Study objective

The aim of this study is to characterize the immune system and its changes over time. We aim to identify the factors that influence the kinetics of immune system aging, to describe potential aging endotypes in different individuals, and correlate them to functional immunological and clinical outcomes

Study design

A single-center, observational prospective cohort study in the Netherlands. Participants from priorly established cohorts will be invited to join the EVIA-study. We will obtain demographic and basic clinical data and biological samples (blood and stool) at baseline and after three years, with a short,

yearly online questionnaire in between.

Study burden and risks

This trial does not include groups that are considered vulnerable, or any intervention. Although venous puncture is an invasive measurement and has some risks (e.g. formation of a hematoma), these are considered negligible. The amount of blood drawn (85ml per timepoint) is not expected to have any negative consequences. The questionnaires employed are general and do not contain questions about particularly sensitive subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Aged between 18 and 60 years;
- Able to communicate orally in Dutch or English;
- Able to give informed consent.

Exclusion criteria

- Any systemic disease or condition, or the use of systemic medication, with the exception of the following:
o Cardiovascular disease and related medication
o Metabolic syndrome, including diabetes, hypertension, and hyperuricemia
- Pregnancy at inclusion (will be recorded during study);
- Acute illness or fever <1 month before inclusion;
- Received vaccines or antibiotics 3 months before inclusion;
- Participation in an intervention trial;
- Legally incapacitated or unwilling to provide informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-10-2024
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	01-07-2024
Application type:	First submission

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	NL86288.091.24