LongitUdinal assessments for early detection of Cardiovascular dIsease in blood Donors

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Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48186

Source
ToetsingOnline

Brief title
LUCID

Condition

- Myocardial disorders

Synonym
Cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Jaap Schouten Foundation

Intervention

Keyword: Biomarkers, Blooddonors, Coronary heart disease

Outcome measures

Primary outcome

The primary study endpoint is incidence of cardiovascular disease, comprising both CHD and HF events. This endpoint is defined as cardiovascular death, or a hospital admission for an acute coronary syndrome (ACS), percutaneous coronary intervention (PCI), coronary artery bypass surgery (CABG), or newly diagnosed HF.

The main study parameters are the blood biomarkers, these will be determined batch wise after all blood samples are collected.

Secondary outcome

Secondary study endpoints will include the individual components of the primary endpoint (cardiovascular death, non-fatal CHD, myocardial infarction, hospitalization for newly diagnosed HF) and combinations thereof, as well as all-cause mortality. Secondary study endpoints will also include a variety of donation-related endpoints (e.g. iron and protein deficiencies), neurological disorders (including dementia and stroke), cancers (including breast cancer, colon cancer, prostate cancer), haematological disorders, kidney disorders, pulmonary disorders, gastrointestinal diseases and liver disorders.

Study description

Background summary

Acquired heart disease remains a major healthcare problem: coronary heart disease (CHD) and heart failure (HF) are both among the top five leading causes of death in the Netherlands. Biochemical markers (biomarkers) in the form of plasma proteins represent major underlying pathophysiological mechanisms and may monitor subtle changes in the heart that reflect and possibly predict adverse changes before they become clinically apparent. Previous studies within the Erasmus MC have shown that a study design with high frequency repeated biomarker sampling is valuable for prognostication in CHD and HF patients. This suggests that such an approach may be valuable for the prediction of incident CHD and HF in persons without clinically manifested disease as well. A group ideally suited to evaluate this hypothesis using the repeated measurements design is the Dutch donor population.

Study objective

The primary objective is to study the association between baseline (including genetic), and repeatedly measured blood biomarkers (including metabolomics and proteomics), and the incidence of cardiovascular disease. Secondary objectives are related to donor health, neurological disorders, cancer, haematological disorders, kidney disorders, pulmonary disorders, gastrointestinal diseases and liver disorders.

Study design

This is a prospective cohort study of whole blood and plasma donors in the Netherlands. Donors will be recruited in the eight XL-locations (with 6000-10,000 donors annually) of Sanquin during one year. They will be followed-up for a maximum of three years. Blood samples will be taken from the sampling bag as part of regular blood/plasma donations at baseline and at every subsequent six months. Donors will also fill in a baseline questionnaire, and a follow-up questionnaire at each subsequent study visit.

Study burden and risks

Risks for this study are low. Venepuncture is the most invasive procedure, but is also part of the standard donation procedure and does not introduce risk other than minor bruising.
There are no individual benefits of participation, besides the contribution to obtaining scientific knowledge for the future.

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

50 years or older
Active donor (two or more donations in year before inclusion)
One or more cardiovascular risk factor (smoker, obesity BMI 30 or higher, hypertension or antihypertensive medication, hypercholesterolemia or statin use, type 2 diabetes or medication, family history of cardiovascular disease before 65 years

Exclusion criteria

Donors that do not master the Dutch language will be excluded

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	5000
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-07-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL69934.078.19