Study of biomarker profiling to unravel the intertwined pathophysiology of coronary artery disease and abdominal aortic aneurysm

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

Summary

ID

NL-OMON53081

Source
ToetsingOnline

Brief title
BIOMArCS-AAA

Condition

- Aneurysms and artery dissections

Synonym
Abdominal aortic aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Stichting Lijf en Leven

Intervention

Keyword: Abdominal aortic aneurysm, Biomarkers, Coronary artery disease, Epidemiology

Outcome measures

Primary outcome

The primary study endpoint is volume of the aneurysm sac, measured repeatedly by CT scan imaging during 24 months of follow-up.

Secondary outcome

Secondary endpoints include maximal diameter and length of the aneurysm, all-cause mortality, quality of life and depression and:

- AAA-related adverse events in watchful waiting group: AAA related death, AAA rupture, or any AAA-related intervention.

- AAA-related adverse events in EVAR patients: direct (type 1 or 3) or undetermined type endoleaks, migration >10 mm, device integrity failure, AAA-related death, late postimplantation AAA rupture, or any AAA-related secondary intervention.

- Cardiovascular events: i.e. cardiovascular death, myocardial infarction, percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG).

Study description

Background summary

Abdominal aortic aneurysm (AAA) is defined as a permanent localized dilatation of the abdominal aorta; a progressive disease with rupture as most disastrous

complication. AAA size alone does not always accurately predict the risk of rupture. Further research is needed in order to install timely and personalized treatment. Blood biomarkers are capable of detecting subtle changes in the pathophysiological processes underlying AAA and can be easily measured. Use of serial biomarker measurements may provide information on individual patterns and may aid in AAA prognostication. Given the overlap in biological systems involved, this may particularly apply to those blood biomarkers that have already proven to be of value in coronary artery disease (CAD). Genetic factors also contribute importantly to AAA. Blood biomarkers of known genetic causes of AAA may also aid in explaining and predicting differences in clinical manifestations of AAA like growth patterns and risk for rupture.

Study objective

The primary objective is to assess the associations of (temporal patterns of) blood biomarkers with aneurysm growth in patients with AAA, with particular attention to biomarkers that have demonstrated prognostic value for adverse disease outcomes in CAD and biomarkers for the main genetic pathways associated with AAA.

Study design

This study is an observational, single center study. Patients with AAA will be recruited through the vascular surgery outpatient clinic of Erasmus MC. The prospective, longitudinal part of the study will include an arm with 120 AAA watchful waiting patients and an arm with 120 AAA patients undergoing endovascular aneurysm repair (EVAR), both with a 24-month follow-up period. Clinical data collection and blood sampling will be conducted at baseline, at 1 month after EVAR and at 6, 12, 18 and 24 months for all patients. CT will be conducted at baseline and 12 and 24 months, plus at 1 month in the EVAR patients. Quality of life and depression questionnaires will be performed at baseline, at 12 and 24 months of follow-up in all patients, and at 1 month only in EVAR patients. Additionally, a cross-sectional study will be performed in 200 patients treated for AAA with EVAR in the past years. In these patients, clinical data collection, blood sampling, ultrasound (including 2D and 3D images) and CT will be performed at their next regular outpatient clinic visit.

Study burden and risks

This is an observational study that does not interfere with regular treatment. The main burden of this study consists of extra visits to the outpatient clinic. However, by combining the study visits with the planned outpatient clinic visits, this will be kept to a minimum of about three times. Procedures during the study visits include obtaining clinical data, blood sampling, ultrasound imaging (for cross-sectional patients), periodical CT scan imaging and periodical questionnaires. CT imaging performed as part of standard medical

care will be used for our research purposes in the EVAR patients, with at most 1 CT scan on top of usual care. In the watchful waiting patients, up to 3 CT scans will be performed on top of usual care (which consists of echocardiographic follow-up). To avoid complications of contrast and to limit the additional ionizing radiation to a minimum, additional CTs performed solely for research purposes will comprise non-contrast CT scans, and radiation exposure will be minimized to 3.2 mSv per CT scan by optimizing equipment settings.

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

This study will include: 1. patients with an AAA diameter >=40mm and treated by watchful waiting strategy; 2. patients planned to undergo EVAR; 3. patients who

underwent EVAR in past years.

Exclusion criteria

Main exclusion criteria: patients with saccular abdominal aortic aneurysm, isolated iliac artery aneurysm, traumatic aneurysm, anastomotic aneurysm and infectious aneurysm, clinical diagnosed thoracic aneurysm, dialysis dependent patients, women of childbearing age or patients with coexistent condition with life expectancy <=1 year.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-03-2017
Enrollment:	440
Type:	Actual

Ethics review

Approved WMO Date:	13-02-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-06-2017

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-07-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-07-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-08-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-04-2022
Application type:	Amendment
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	NL60075.078.16