Biomarker assessment in adults with thoracic aortic aneurysm or dissection

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To identify which patient characteristics and biomarkers can contribute to a better prediction of complications in patients with thoracic aortic disease. This will result in better risk-prediction with reassurance of low-risk individuals and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON45356

Source
ToetsingOnline

Brief title
BioTAAD

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Aneurysms and artery dissections

Synonym
Thoracic aortic aneurysm, thoracic aortic dilatation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anxiety, Biomarker, Depression, Thoracic aortic aneurysm, Thoracic aortic dissection

Outcome measures

Primary outcome

The main study parameter will be increase in dimension of the aorta.

Secondary outcome

Secondary study parameters/endpoints are mortality, need for interventions and complications (aortic dissection). Also the incidence of anxiety/depression and the quality of life of patients and partners or family members will be secondary endpoints.

Study description

Background summary

Thoracic aortic aneurysm (TAA) prevalence in the Netherlands is estimated at 200.000 adults, with annually 600 deaths of aortic dissection or rupture. To prevent aortic dissection and sudden death, timely intervention is warranted. The indication for preventive surgery is presently based on the underlying diagnosis and aorta diameter. It is unknown to what extent biomarkers can contribute to the selection of patients at high risk. Also in clinical practice we experience anxiety and depression in patients with thoracic aortic disease and their partners or family members with great impact on quality of life. However, without objective evidence.

Study objective

To identify which patient characteristics and biomarkers can contribute to a better prediction of complications in patients with thoracic aortic disease. This will result in better risk-prediction with reassurance of low-risk individuals and intensive follow-up with earlier surgical correction in high-risk individuals. In addition we want to investigate the burden of anxiety and depression in these individuals and their partners and family members to see if this is indeed a problem and to identify possibilities for better

patient-tailored guidance and assistance.

Study design

A prospective, observational cohort study with invasive measurements (blood samples) and three questionnaires.

Study burden and risks

For this study, blood samples (8 tubes, 46 mL blood) will be obtained ones. Besides the blood sampling, patient and their partners or family members will be asked to fill in the *Hospital Anxiety and Depression Scale* (HADS) questionnaire, the Short Form (36) Health Survey (SF-36) and a disease-specific questionnaire to investigate the impact of TAA on normal life. In 20 patients we will perform an in-depth interview. All other investigations in this study are part of routine clinical care. Therefore, risks for the patients can be considered negligible.

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

- Scheduled for an appointment at the outpatient department for thoracic aorta disease in the Erasmus MC
- Thoracic aorta pathology with or without known genetic mutation
- Receiving imaging of the aorta with use of echocardiography or computer tomography (CT)
- Capable of understanding and signing informed consent.

Exclusion criteria

- Patients who are not capable of understanding and signing informed consent.
- Age <18 years.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2017
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	28-03-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-07-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-01-2018
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	NL59759.078.17