Predicting aneurysm growth and rupture with longitudinal biomarkers

Published: 25-08-2017
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Primary Objectives: •To determine the correlation between AAA growth and the evolution of serum levels of proteases and cytokines.•To determine the correlation between AAA rupture and the evolution of serum levels of proteases and cytokines.•To...

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

Summary

ID

NL-OMON49399

Source
ToetsingOnline

Brief title
PARIS-study & Pearl AAA

Condition

- Aneurysms and artery dissections

Synonym
Abdominal aortic aneurysm; local enlargement of the main abdominal artery

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC Foundation

Intervention

Keyword: Abdominal, Aneurysm growth, Aneurysm rupture, Aortic Aneurysm, Biomarkers

Outcome measures

Primary outcome

Primary study parameters/outcomes

•AAA growth (mm/y). This will be measured using repeated imaging with either ultrasound, CT or MRI.

•AAA rupture. This is defined as acute haemorrhage from the aneurysm outside the true aortic wall with the presence of intra-peritoneal and/or retroperitoneal blood at imaging, or observed during repair.

•Death

•Serum levels of cytokines (including, but not limited to IL- 6)

•Serum levels of proteases (including, but not limited to MMP-9)

•Protease and cytokine levels in aortic tissue

Secondary outcome

Secondary study parameters/outcomes

•During the course of the study, additional study parameters will be collected, as part of regular clinical care. For a full overview of all study parameters collected, please see the clinical data items titled PRISMA. PRISMA will contain all parameters collected during this project. Due to the longitudinal nature of this project, PRISMA may be subject to change.

•Incidence of complications after AAA repair

•Type of complications after AAA repair

Study description

Background summary

Abdominal aortic aneurysms (AAAs) are local dilatations of the abdominal aorta. They are generally asymptomatic, but can grow or eventually rupture. AAA rupture is associated with high morbidity and mortality. Therefore, current treatment is to prevent rupture through aneurysm repair. The decision to carry out this repair is based on aneurysm diameter, since aneurysm with a larger diameter have a higher rupture risk. However, aneurysm diameter is not a very reliable predictor of rupture. Therefore, further research has focused on elucidating the pathogenesis of aneurysm progression in order to identify additional predictors of growth and rupture.

Study objective

Primary Objectives:
•To determine the correlation between AAA growth and the evolution of serum levels of proteases and cytokines.
•To determine the correlation between AAA rupture and the evolution of serum levels of proteases and cytokines.
•To determine the correlation between overall survival and the evolution of serum levels of proteases and cytokines.
•To determine the correlation between serum levels of proteases and cytokines and levels of proteases and cytokines in aortic tissue.

Secondary Objectives:
•To create a new biobanking infrastructure that will enable future research initiatives focusing on the identification of other factors involved in AAA pathogenesis. Additional biomaterials, images and clinical data will be collected in extension of this study; in a biobank, imagebank and databank, respectively.
•To determine the incidence of complications after AAA repair.
•To characterize the complications after AAA repair.

Study design

A prospective multicentre observational cohort study

Study burden and risks

There is no direct benefit for the participants. This is a longitudinal study in which patients will be followed-up for many years, for as long as their AAA treatment is continued. This may mean that a participant is followed-up for life. In addition to the regular clinical treatment, biomaterials, imaging data

and clinical data will be collected and saved. The biomaterials consist of venous blood and urine. Also, in the few cases where conventional open surgery is indicated, AAA tissue samples will be collected. Collection of AAA tissue is without risks. The frequency of biomaterial collection will be in accordance to the frequency of regular clinical hospital visits. The imaging data will consist of CT and MRI images that have been generated as part of regular clinical practice. Clinical data will be obtained during regular patient visits to the hospital.

Some of the patients will be included while they are decisionally impaired due to the effects of an acute AAA. These patients represent an important clinical outcome in the natural history of AAA and are therefore included. Such information cannot be learned from patients who do not have an acute AAA. The risks and burden while a patient is decisionally impaired is minimal. To instigate treatment of these patients, venous blood will already be drawn for clinical diagnosis and all patients get a urinary catheter to prevent urinary retention during treatment.

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

- Adult person (18 years or older)
- Person has an abdominal aortic aneurysm or has previously been treated for an abdominal aortic aneurysm
- Adequate comprehension of the Dutch language to provide written informed consent

Exclusion criteria

- A patient who is decisionally impaired. The only exception to this are patients who are decisionally impaired due to effects of an acute abdominal aortic aneurysm. This particular group is eligible for participation

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):	04-10-2017
Enrollment:	750
Type:	Actual

Ethics review

Approved WMO Date:	25-08-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Not approved Date:	11-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2021
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	NL59991.018.17

Study results

Results posted: 10-05-2022

First publication
01-01-1900