Longitudinal study to pulsatility and expansion in aortic stent grafts

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Information on the dynamics and shape of the device and how these change over time will improve our understanding about the fixation of the device, which may help in stent selection and in designing stent grafts that are more durable.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Aneurysms and artery dissections
Study type	Observational non invasive

Summary

ID

NL-OMON44847

Source
ToetsingOnline

Brief title
LSPEAS

Condition

- Aneurysms and artery dissections

Synonym
AAA, Aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Terumo,Vascutek Ltd.

Intervention

Keyword: expansion, longitudinal, pulsatility, stent graft

Outcome measures

Primary outcome

Of primary interest are the changes in the diameter of the stent ring due to hemodynamic forces. We distinguish between changes during the heartbeat (pulsatility) and changes over a period of several months (expansion).

Secondary outcome

* How does the estimated vessel compliance change over a period of several months?

* Can we observe other kinds of motion that change over time?

Study description

Background summary

Endovascular aortic replacement (EVAR) uses stent grafts to treat aortic aneurysms in patients at risk of aneurysm rupture. The long-term durability of these stent grafts is hindered by complications requiring reintervention. As most self-expanding stent grafts rely on oversizing in order to provide sufficient sealing, the decision for the device size is critical. Once implanted, the aorta dynamics and the device affect each other in ways that are currently not understood. Pre- and post-operative imaging of aortic aneurysm is routinely performed using computerised tomographic angiography (CTA). However, these static techniques do not consider the aorta dynamics. Consequently, measurements on the vessel diameter are relatively inaccurate, and our understanding of the dynamic behaviour of the stent is limited. ECG-gated CTA is a technique that takes the patient*s heart cycle into account, enabling studies to the motion of aorta and implanted devices.

Study objective

Information on the dynamics and shape of the device and how these change over time will improve our understanding about the fixation of the device, which may

help in stent selection and in designing stent grafts that are more durable.

Study design

Explorative observational cohort study with aortic abdominal aneurysm (AAA) patients undergoing endovascular repair (EVAR) with Anaconda or Endurant stent grafts.

Study burden and risks

The ECG-gated CTA protocol results in a higher dose in comparison to a routine scan. However the additional risk on the chance of acquiring cancer as a result of this higher dose is estimated to be negligible, because the study population has a low life expectancy and only patients above 70 will be included.

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

* Asymptomatic AAA
* Age > 70
* Indication for AAA treatment according to standard practise
* Anatomy suitable for Anaconda and/or Endurant endoprosthesis

Exclusion criteria

* No informed consent obtained

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	03-03-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	16-03-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	16-06-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Not approved Date:	17-11-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL47038.044.13