Longitudinal study on pulsatility and expansion in aortic stent grafts after Fenestrated Endovascular Aneurysm Repair

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Information on the dynamics and shape of the stent graft and stented target vessels and how these change over time will improve our understanding about the fixation and/or sealing of the device, which may help in stent graft selection and in...

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

Summary

ID

NL-OMON49129

Source
ToetsingOnline

Brief title
LSPEAS F-EVAR

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,Terumo Aortic en Health~Holland

Intervention

Keyword: expansion, fenestrated stent graft, longitudinal, pulsatility

Outcome measures

Primary outcome

Of primary interest are the changes in the diameter of the stent ring due to hemodynamic forces and the changes in the dynamic interaction between the main body, the branches, and the renal and/or mesenteric arteries. We distinguish between changes during the heartbeat (pulsatility) and changes over a period of several months (expansion).

Secondary outcome

* How does implantation of the Fenestrated Anaconda* stent graft with stenting of the target vessels influence the movement of the aorta, renal arteries and mesenteric arteries? * 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

Fenestrated endovascular aortic repair (F-EVAR) uses stent grafts with customized fenestrations to treat complex aortic aneurysms in patients at risk of aneurysm rupture. The long-term durability of these stent grafts is hindered by complications requiring reintervention. Especially the perirenal fixation and sealing area is of vital importance. The customized fenestrations in the stent graft are cannulated with stents into the renal and/or mesenteric arteries, challenging the perirenal fixation. 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, our understanding of the dynamic behaviour of the stent graft and stented target vessels 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 stent graft and stented target vessels and how these change over time will improve our understanding about the fixation and/or sealing of the device, which may help in stent graft selection and in designing stent grafts that are more durable

Study design

Explorative observational cohort study with patients with an aortic abdominal aneurysm (AAA) undergoing endovascular repair with the fenestrated Anaconda* stent graft (F-EVAR).

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 65 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 > 65 * Indication for AAA treatment according to standard practise * Anatomic suitability for the Fenestrated Anaconda* stent graft * At least one stentable main renal artery and one other stentable renal or mesenteric artery

Exclusion criteria

No informed consent obtained * eGFR < 30 ml/min * Allergy for intra venous contrast fluid

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	07-02-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	fenestrated endoprothesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-01-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-05-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-07-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-09-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24358
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59794.044.16
Other	NTR- [te ontvangen identificatienummer]
OMON	NL-OMON24358

Study results

Date completed:	15-12-2021
Actual enrolment:	21