

Longitudinal study to changes in shape and motion of the aorta and endoprosthesis after fenestrated endovascular aneurysm repair

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24358

Source

NTR

Brief title

LSPEAS F-EVAR

Health condition

Complex abdominal aortic aneurysm
Uitgebreid abdominaal aorta aneurysma
Uitgebreid verwijde buikslagader

Sponsors and support

Primary sponsor: University of Twente

Source(s) of monetary or material Support: University of Twente

Intervention

Outcome measures

Primary outcome

To gain insight in the parameters that influence the success and failure of the proximal fixation and/or sealing of the Fenestrated Anaconda™ stent graft.

More practically, this leads to the questions of how the diameter of the stent rings changes during the cardiac cycle (pulsatility), how the diameter changes over a period of several months (expansion) and how the stent graft with stented fenestrations interacts with the dynamics of the stented target vessels.

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

Rationale: 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.

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 stent graft, which may help in stent graft 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 with the fenestrated Anaconda™ stent graft (F-

EVAR).

Study population: The study population consists of 20 patients with an AAA to be treated with F-EVAR, aged >65.

Intervention: Present practise is that all patients with a complex AAA undergo CTA of the abdominal aorta pre-operatively and post-operatively before discharge or after 6 to 8 weeks, after 3 to 6 months, after 12 months, and yearly thereafter. Patients included in this study receive an ECG-gated CTA before intervention and three ECG-gated CTs post-operatively: at discharge, after 6-8 weeks, and after 12 months. Thereafter the routine follow up scheme will be followed.

Main study parameters/endpoints: 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). By relating the observed motions to computational models of the stent and the biomechanics of the vessel wall, the change in vessel compliance can be estimated.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

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 stent graft, which may help in stent graft selection and in designing stent grafts that are more durable.

Study design

- Inclusion of patients complete

- Each included patient is scanned pre-operatively and three times post-operatively until 12 months follow-up.

Intervention

Present practise is that all patients with a complex AAA undergo CTA of the abdominal aorta pre-operatively and post-operatively before discharge or after 6 to 8 weeks, after 3 to 6 months, after 12 months, and yearly thereafter. Patients included in this study receive an ECG-gated CTA before intervention and three ECG-gated CTs post-operatively: at discharge, after 6-8 weeks, and after 12 months. Thereafter the routine follow up scheme will be followed.

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Eligibility criteria

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 non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49129
 Bron: ToetsingOnline
 Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6078
NTR-old	NTR6225
CCMO	NL59794.044.16
OMON	NL-OMON49129

Study results

Summary results

N/A