Longitudinal study to changes in shape and motion of the aorta and endoprosthesis after fenestrated endovasculair 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 stent graft, which may help in stent graft selection and in...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24358

Bron
Nationaal Trial Register

Verkorte titel
LSPEAS F-EVAR

Aandoening

Complex abdominal aortic aneurysm
Uitgebreid abdominaal aorta aneurysma
Uitgebreid verwijde buikslagader

Ondersteuning

Primaire sponsor: University of Twente
Overige ondersteuning: University of Twente

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

-Inclusion of patients complete

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

Onderzoeksproduct en/of interventie

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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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• No informed consent obtained

• eGFR < 30 ml/min

• Allergy for intra venous contrast fluid

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49129
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A