LSPEAS

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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 and/or sealing of the device, which may help in stent selection and in designing stent grafts that are more durable.

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

Samenvatting

ID

NL-OMON21575

Bron
NTR

Verkorte titel
LSPEAS

Aandoening

abdominal aneurysm
stent graft

Ondersteuning

Primaire sponsor: Vascutek Ltd.
Overige ondersteuning: Vascutek Ltd.

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 endoprosthesis.

More practically, this leads to the question of how the diameter of the stent rings changes during the cardiac cycle (pulsatility), and how the diameter changes over a period of several months (expansion)?

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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 patientâ€™s heart cycle into account, enabling studies to the motion of aorta and implanted devices.

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

Study design: Patients selected for endovascular repair (EVAR) using the Anaconda or Endurant device receive multiple ECG-gated CTAâ€™s. The resulting data is processed to measure the shape and motion of the device at surgically relevant locations.

Study population: The study population consists of 20 aortic abdominal aneurysm (AAA) patients selected for EVAR with Anaconda or Endurant endoprostheses. Only patients aged > 70 and with an eGFR > 60 ml are included.

Intervention: Present practise is that all AAA patients undergo one abdominal aorta CTA pre-operatively, and receive ultrasound duplex scanning and plain abdominal X-ray at discharge, 3 months, 6 months and yearly thereafter; CT-scans are performed on indication. Patients included in this study receive an ECG-gated CTA pre-intervention plus three ECG-gated CTAs

post-operatively: at discharge, after one month, and after six 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. 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. The three extra scans means an overall increase in dose applied to the patient. Further, an ECG-gated scan requires ECG electrodes to be applied before scanning.

Doel van het onderzoek

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

Onderzoeksopzet

The duration of this study is two years and is split in three phases:

1) Three patients are included in the study. Their pre-operative scan is performed with ECG-gating, and one additional ECG-gated scan is performed at discharge. From this information we can determine whether the data is of sufficient quality to perform segmentation and registration;

2) Ten patients are each scanned four times (this includes the three patients from phase one, who thus only need two extra scans in this phase). From this information we should be able to estimate whether the data will lead to the insights that we are after;

3) Another 10 patients are each scanned four times.

Onderzoeksproduct en/of interventie

Present practise is that all AAA patients undergo one abdominal aorta CTA pre-operatively, and receive ultrasound duplex scanning and plain abdominal X-ray at discharge, 3 months, 6 months and yearly thereafter; CT-scans are performed on indication. Patients included in this study receive an ECG-gated CTA pre-intervention plus three ECG-gated CTAs post-operatively: at discharge, after one month, and after six 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 > 70

- Indication for AAA treatment according to standard practise

- Anatomy suitable for Anaconda and/or Endurant endoprosthesis

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- No informed consent obtained

- Contrast allergy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4074
NTR-old	NTR4276
Ander register	: 47038
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A