Feasibility assessment of the prophylactic Use of AneuFix at the time of EVAR implantation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Aneurysms and artery dissections
Study type	Interventional

Summary

ID

NL-OMON54373

Source
ToetsingOnline

Brief title
AneuFix - PSF

Condition

- Aneurysms and artery dissections

Synonym
Endoleak, Leak

Research involving
Human

Sponsors and support

Primary sponsor: TripleMed B.V.
Source(s) of monetary or material Support: TripleMed b.v.

Intervention

Keyword: AAA (Abdominal Aortic Aneurysm), Endoleak, EVAR, Polymer

Outcome measures

Primary outcome

- Technical feasibility of Prophylactic Sac Filling using AneuFix

- Absence of aneurysm sac growth at 6 and 12 months (Clinical success)

Secondary outcome

- Intraoperative occurrence of complications

- Rate of peri-operative complications (<30 days)

- Occurrence of (any type) endoleak

- Occurrence of adverse events and adverse device effects at 1, 6 and 12 months

- Rate of secondary endovascular or surgical re-interventions at 1, 6 and 12

months

- Rate of aneurysm rupture at 6 and 12 months

- Survival throughout the study up until 24 months

Study description

Background summary

Endovascular aortic aneurysm repair (EVAR) has become a well-established treatment modality for most abdominal (infra-renal) aortic aneurysms (AAA) repair. EVAR, however, has a number of disadvantages. Complications and reinterventions caused mainly by endoleaks, endotension and stent-graft migration, and device failure are of major concern. As a result, lifelong follow-up is needd since these complications can be associated with aneurysm rupture. The most important complications of EVAR are the possible occurrence of endoleaks, of which type II endoleaks are the most common. To prevent this type of endoleaks, papers currently describe the method of IMA (inferior mesenteric artery) embolization or embolization of large open lumbar arteries.

Typically these methods reduce the incidence of endoleak occurrence and sac growth by between 25-50%.

The main conclusions from the literature review are:
• Type II endoleaks are frequently occurring post-EVAR; but most resolve spontaneously in case of early type II endoleaks <6 months
• Only in situations of persistent type II endoleaks >6 months where the aneurysm sac is growing as a result of the presence of type II endoleaks, reinterventions are to be considered
• The technical success rates of interventions are typically high: >80%
• The clinical success rates (sac growth stabilization or decrease) over more than 1 year are typically low: <60%
• None of the current treatment techniques offers the ultimate good solution
• Reinterventions to treat a type II endoleak are expensive
• Preventing endoleaks by embolizing only the IMA or patent lumbars >2mm have only limited clinical success
• Filling the complete aneurysm sac with a polymer at the moment of EVAR shows promising results for prevention of endoleaks, as demonstrated in the Nellix clinical studies

Our hypothesis from the literature is therefore that all of the potential causes for type II endoleak have their role: a patent IMA, patent lumbars, size and shape of the aneurysm sac and thrombus present. We therefore postulate that if we want to obtain a near 100% reduction of the occurrence of endoleak type II and aneurysm sac growth, we need to occlude all in/outflow blood vessels as well as obtain a complete filling of the aneurysm sac.

Study objective

The leading hypothesis is: Endoleaks type II are prevented when AneuFix is prophylactically used during EVAR procedures.
The primary (performance) objective is to assess the feasibility to fill the AAA sac after EVAR during the same procedure, and to assess the rate of endoleaks after EVAR followed by the AneuFix procedure.
The secondary objective of the study is to assess the occurrence of type II endoleaks at 6 and 12 months after EVAR, and aneurysmal sac growth at 6 and 12 months after EVAR. In the analyses we will compare the occurrence rates of type II endoleaks and sac growth between historical control and prophylactically treated patients.

Study design

To obtain evidence needed for a successful CE mark submission, data of sufficient patients are needed. For this a non-randomized, international, multi-center safety and performance trial will be set up. However, before initiating this study we first want to execute a pilot study. In the pilot

study a maximum of 15 patients will be treated in a multiple Dutch medical centers including AUMC. Aim of the pilot study is to define and evaluate the feasibility of the clinical procedure of Prophylactic Sac Filling (PSF). The treatment results of the maximum 15 patients will be reviewed by the DSMB and used to ask METC approval for the follow-on study.

Intervention

After placement of the EVAR stent graft through openings in both groins, one additional sheath is inserted through the groin along the stent into the aneurysm. With the help of x-ray, it is seen whether the sheath has been inserted in the right place and it is possible to measure how large the aneurysm is. This measurement is needed to determine how much AneuFix material is needed to fill the aneurysm. AneuFix is injected through this sheath.

Study burden and risks

The extra burden for the patients who participate in the study is limited to two extra outpatient clinic visits (screening) compared to the standard follow up of the patients. In addition, the Aneufix injection is an extra burden as the standard EVAR procedure will take (about 20 minutes) longer than normal. The risks associated with participation of the study are related to this injection procedure, and the correct filling of the aneurysm sac without off-target embolisation and deformation of the endograft. The polymer itself is biocompatible, so no risks of presence of Aneufix in the body are expected. The only disadvantage is the presence of tantalum for visibility during the injection procedure, which will make the EVAR invisible for future imaging when necessary.

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, infrarenal AAA that requires surgery with a high-risk profile of developing
endoleak type II in line with the recommendations of Fabre et al:
• a patent IMA, with a luminal diameter at its origin > 3 mm, OR
• at least three pairs of patent lumbar arteries, or two pairs of lumbar arteries and a median
sacral artery or an accessory renal artery.
• Infrarenal neck according to the IFU of the EVAR device
• Other aortic-iliac anatomical configuration suitable for EVAR according to the criteria of the
EVAR device to be used
• Patient having a life expectation of at least 2 years
• Being older than 18 years
• Willing and able to comply with the requirements of this clinical study

Exclusion criteria

1. Patient not able or willing to give written Informed Consent
2. Patient undergoing emergency procedures
3. Patient undergoing EVAR for ruptured or symptomatic AAA,
4. Patient with a suprarenal AAA
5. Patient with an inflammatory AAA (more than minimal wall thickening)
6. Patient with an infrarenal neck unsuitable for endovascular fixation (including so called *hostile necks*) or aortic-iliac anatomic configuration otherwise unsuitable for EVAR according to criteria of the device to be used
7. Patient in which a bilateral retroperitoneal incision is required for EVAR
8. Patient in which a sacrifice of both hypogastric arteries is required

9. Patient with anatomical variations
10. Patient in which the administration of contrast agent is not possible: proved, severe systemic reaction to contrast agent
11. Patient with active infection present
12. Patients scheduled for or having received an organ transplant
13. Patient with limited life expectation due to other illness (<1 year)
14. Patient with non-iatrogenic bleeding diathesis
15. Patient with connective tissue disease
16. Women of child-bearing potential
17. Patients with evidence at completion angiogram during EVAR of a type Ia or type III endoleak persistent after balloon inflation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2021
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	The endovascular aneurysm implant (AneuFix) is an implantable device intended for long term use and
Registration:	No

Ethics review

Approved WMO

Date:	22-07-2020

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-11-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-12-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT04307992
CCMO	NL73223.029.20