Treatment of type II Endoleaks with ANEUFIX: assessment of safety, performance and clinical benefit..

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

Summary

ID

NL-OMON55992

Source
ToetsingOnline

Brief title
Aneufix for Edoleak TII

Condition

- Aneurysms and artery dissections

Synonym
Persistent leak

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Endoleak Type II, Feasibility, Polymer

Outcome measures

Primary outcome

Primary end-point is defined as *Technical success of Type II endoleak repair with ANEUFIX as demonstrated by the absence of endoleak circulation at the intended treated endoleak at the end of the procedure*. The presence or absence of the endoleak treated with Aneufix is verified by means of a CT scan the next day.

Secondary outcome

The secondary end-points are defined as:

- Absence of aneurysm sac growth at 6, 12 and 24 months (determination of clinical success rate via CT scans). Growth is determined based on independent imaging core lab assessments of the abdominal aortic diameter, measured as the maximum diameter relative to the aneurysm;

- Documentation of intra- and peri-operative complications (<30 days);

- Occurrence of serious adverse events, vascular related adverse events and adverse device effects: complications and deaths, re-interventions, aneurysm rupture in the peri operative period.

- Occurrence of general adverse events and adverse device effects at 1 week, and 1 month, 6, 12 and 24 months;

- Rate of secondary endovascular or surgical re-interventions at 1, 6, 12 and 24 months;

- Rate of aneurysm rupture at 6, 12 and 24months;

- Survival throughout the study up until 24 months.

Safety is assessed based on the nature and severity of adverse events.

The secondary end-point of aneurysm sac growth will be assessed by means of CT-scan at the 6, 12 and 24 month follow up, and be based upon the measurement of the diameter of the AAA-sac. It is anticipated that no AAA-sac growth will be observed in minimally 80% of those patients where the procedure is successfully executed. The AAA sac growth will be re-assessed by an independent core lab. All other safety related adverse events are documented and adjudicated by the DSMB.

Study description

Background summary

Endovascular aortic aneurysm repair (EVAR) has become a well-established treatment modality for infrarenal abdominal aortic aneurysms (AAA) repair. EVAR, however, might be associated with some complications. Complications and re-interventions caused by endoleaks, stent-graft migration, or device failure (in general) are of major concern. As a result, lifelong imaging follow-up is needed since these complications can be associated with late aneurysm rupture. The major complication with EVAR is the potential occurrence (early or late) of endoleaks. Different types of endoleaks are described with different incidences and different levels of impact. A recent article (Mees et al. 2013) list current endoleak type II treatments, incidences, clinical outcomes. The article concludes that few endoleaks of this type II require treatment in view of the relative low clinical success rates, the high morbity and even high mortality rates of some (surgical) interventions: a conservative management is advised, definitely when no aneurysm sac growth is observed.

Despite the high incidence of endoleak type II (in about 30% of EVAR-patients), even associated with the occurrence of aneurysm sac growth (in about 6% of EVAR-patients), the treatment success of type II endoleaks are disappointing.

Conclusions of literature review:
1. Type II Endoleaks are frequently occuring post-EVAR; but frequently resolve spontaneously in case of early type II endoleaks < 6 months
2. 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;
3. The technical success rates are typically high: >80%
4. The clinical success rates (sac growth stabilization or decrease) over more than 1 year are typically low: <60%;
5. None of the current treatment techniques offers the ultimate good solutionclinical success;
tion techniques are more and more used also for Type I Endoleak treatments whereby larger volumes of up to 20 ml are used to create the cast.

The current study aimes to come to a succesfull, safe and technical feasible treatment of endoleaks type II and to open the way for research of the treatment of endoleaks type I.

Study objective

The primary (performance) objective of the study is to assess the feasibility to treat repair type II endoleaks with ANEUFIX successfully, which is called *technical success*.

The secondary objective of the study is to assess the clinical success rate (clinical benefit objective) and to observe, document and handle occurring complications well (safety objective).

Study design

The study is a non-randomized, international, multi-center safety and performance trial. Aneufix is applied in 57 patients suffering from endoleak type II requiring an intervention.Clinical benefit of the ANEUFIX procedure is demonstrated by the absence of aneurysm sac growth and thus the reduced risk for death.

Intervention

The aneurysm sac is punctured via a trans-lumbar approach under CT-guidance. A large bore introduction sheath (minimal 4 Fr) is positioned. Aneufix is injected under fluoroscopic control to fill the endoleak void, including the nidus of the artery causing the leak and of the relevant draining artery.

Study burden and risks

The extra burden for the patients who participate in the study is limited to

two extra outpatient clinic visits (screening, baseline) compared to the standard follow up of the patients. In addition, the procedure where Aneufix is injected is an extra burden. This will be performed via translumbar injection under CT guidance. The risks associated with participation of the study are related to this injection procedure. 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 fo 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

1. Persistent type II endoleak (more than 6 months post-EVAR or

post-embolization procedure); AND
2. Volume of the 'endoleak void' can be estimated upfront; AND
3. An endoleak confirmed on a CT scan that should be done within 180 days prior to procedure but preferably within 90 days prior to screening demonstrating the high likelihood of the isolated nature of the endoleak; AND
4. An aneurysm sac growing after EVAR of minimal 10 mm (per European Guidelines) as documented in the preceding 90 days by means of CT-imaging (alternative imaging technique) and based upon sac diameter measurements; AND
5. An aneurysm sac that can be punctured in translumbar approach; AND
6. Possibility to withhold anti-thrombogenic medication temporarily; AND
7. Ability and willingness to undergo the translumbar procedure; AND
8. Be older than 18 years.

Exclusion criteria

1. Patient not able or willing to give written Informed Consent themselves; OR
2. Patient undergoing emergency procedures; OR
3. Patient with traumatic vascular injury; OR
4. Patient with an untreated endoleak connected to an open AMI (patients can be included if the AMI is coiled or is technically not possible to be coiled prior the Aneufix application); OR
5. Patient with hemostatic disorder (including bleeding disorders) or who is clinically unstable; OR
6. Patient with a too high risk of abdominal sac rupture to allow safe radiological and scanographic assessments; OR
7. Patient who is allergic to contrast media or anticoagulants; OR
8. Patient with renal impairment (eGRF < 30 ml/min); OR
9. Patient with a contra-indication for temporal positioning of a translumbar needle/catheter; OR
10. Patient who is participating in another trial with an investigational drug or medical device or where a medical device/drug is used outside its labelling and its approved intended use; OR
11. Pre-menopausal women, OR
12. Patient with a life expectancy of less than 12 months; OR
13. Patient with an intra aneurysm systolic blood pressure > 125 mmHg

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2020
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Aneufix;which is a 2-component polymer that cures rapidly and which is enriched with a 30% concentra
Registration:	No

Ethics review

Approved WMO Date:	13-02-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-10-2020

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-08-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2023
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
Other	NCT03918460
CCMO	NL69807.029.19