Feasibility study of ANEUFIX : a novel, first in man approach to treat Type II Endoleaks using ACP-T5.

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The primary objective of the study is to assess the feasibility to treat type II endoleaks with Aneufix ACP-T5 successfully.The secondary objectives of the study are to assess the:- Clinical success rate defined as Occurrence of adverse events and…

Ethical review	Not approved
Status	Will not start
Health condition type	Aneurysms and artery dissections
Study type	Interventional

Summary

ID

NL-OMON44932

Source
ToetsingOnline

Brief title
Aneufix ACP-T5

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

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 ACP-T5 as demonstrated by the absence of an endoleak at the end of the procedure*.

Secondary outcome

The secondary end-points are defined as:

- Occurrence of general adverse events and adverse device effects at 1, 3, 6 and 12 months and 24 months;

- Absence of aneurysm sac growth at 6 and12 months (clinical success rate);

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

- Rate of secondary endovascular or surgical re-interventions at 1, 3, 6 and 12 months;

- Rate of aneurysm rupture at 6 and 12months;

- Survival throughout the study

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

Study description

Background summary

Endovascular aortic aneurysm repair (EVAR) has become a well-established treatment modality for abdominal (infra-renal artery) aortic aneurysms (AAA) repair. EVAR, however, has several disadvantages. Complications and re-interventions caused mainly by endoleaks, endotension, stent-graft

migration, and device failure are of major concern. As a result, lifelong follow-up is needed since these complications can be associated with aneurysm rupture. In addition, EVAR has anatomical restrictions.
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, Voute, Bastos Gonçalves, Mota Capitao, & Verhagen, 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 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 and rather in the order of about 25% (Schanzer, et al., 2011) and rarely correctly and fully successfully addressed: freedom from sac growth after repair is the only relevant successful outcome measure (Mees, Voute, Bastos Gonçalves, Mota Capitao, & Verhagen, 2013).

Conclusions of literature review:
1. Type II Endoleaks are frequently occuring post-EVAR. Conservative treatment, i.e. surveillance follow up, seems most appropriate as the risk for sac rupture is low.
2. However, in situations where the aneurysm sac is growing as a result of the presence of Type II Endoleaks, reinterventions are attempted to treat the endoleak with a variety of transarterial or translumbar methods.
3. The typical large variety of methods and techniques applied within a single center (coil, glue, plug,..) is indicative that none of the current techniques offers the ultimate good solution.
4. As reinterventions to treat a Type II Endoleak are expensive (in the order of $40,000 - Jouhannet, et al., 2014), the prevention of it will remain a desire and an ongoing challenge till a simple technique with high success rate and low complication rates becomes available.
5. A reintervention aims also for a long-term effective repair; today the success rates are too low and the purchase costs too high to make the use of embolisation glue (Onyx, Squid) widely and generally applicable, except for its initial intended use.
6. Recently, the same embolization 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 objective of the study is to assess the feasibility to treat type II endoleaks with Aneufix ACP-T5 successfully.

The secondary objectives of the study are to assess the:
- Clinical success rate defined as
Occurrence of adverse events and adverse device effects: complications and deaths, re-interventions, aneurysm ruptures

Study design

The study is a non-randomized, multi-center safety and feasibility trial. Aneufix ACP-T5 is applied in 5 patients suffering from endoleak type II requiring an intervention.
An independent Data Safety Monitoring Board (DSMB) will review the clinical outcome data and decide on the safety of the procedure for each individual enrolled patient. The decision of the DSMB is based on the assessment of severity of intra- and peri-operative (adverse device) effects. A positive outcome of the DSMB meeting is required to continue to enrol the next patient. A one month follow up period for the first patient and a one week follow up period for the other patients is considered for the decision making on the study continuation by the DSMB.

Intervention

The aneurysm sac is punctured via a trans-lumbar approach under CT-guidance by interventional radiologist. Through a 5-7Fr introduction sheath0 a filling and a draining catheter are positioned. ACP-T5 is injected under fluoroscopic control to completely fill the endoleak void, including the nidus of the artery causing the leak.

Study burden and risks

The extra burden for the patients who participate in the study is limited to three extra outpatient clinic visits (screening, baseline and 1 month follow up) compared to the standard follow up of the patients. In addition, the procedure where Aneufix ACP-T5 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 ACP-T5 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

- Persistent type IIa or IIb endoleak (more than 6 months post-EVAR or post-embolization procedure); AND
- Volume of the *endoleak void* can be determined upfront; AND
- An EVAR without circulatory complications; AND
- An endoleak confirmed by CT scan in preceding 8 weeks demonstrating the high likelihood of the isolated nature of the endoleak; AND
- An aneurysm sac either growing in contours after EVAR (per European Guidelines) as documented in the preceding 8 weeks by means of echo (or alternative visualization technique); AND
- An aneurysm sac that can be punctured in translumbar approach from minimally two directions; ANDPossibility to withhold anti-thrombogenic medication temporarily; AND
- Ability and willingness to undergo the translumbar procedure under local anesthesia in a CT

scan
-Patients older than 18 years

Exclusion criteria

- Patient not able or willing to give written Informed Consent; OR
- Patient undergoing emergency procedures; OR
- Patient with traumatic vascular injury; OR
- Patient with hemostatic disorder or who is clinically unstable; OR
- Patient with a risk of abdominal sac rupture too high to allow safe radiological and scanographic assessments; OR
- Patient who is allergic to contrast media or anticoagulants; OR
- Patient with renal impairment (serum creatinine > 2 mg/dl or > 176 mmol/l); OR
- Patient who is participating in another trial with an investigational drug or medical device; OR
- Patient with a life expectancy of less than 12 months.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	Aneufix;more specifically the model ACP-T5;which is a 2-component polymer that cures rapidly and nor
Registration:	No

Ethics review

Not approved

Date:	15-03-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT02487290
CCMO	NL53866.098.15