

# Feasibility study of treatment type II Endoleaks with ACP-T5: a novel approach

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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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Aneurysms and artery dissections
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON48581

### Source

ToetsingOnline

### Brief title

ANEUFIX ACP-T5

### Condition

- Aneurysms and artery dissections

### Synonym

Persisten 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 and 12 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 12 months;
- 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 (infrarenal artery ) aortic aneurysms (AAA) repair. EVAR, however, has several disadvantages. Complications and reinterventions 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 Capitaó, & 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 morbidity 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 Capitaó, & Verhagen, 2013).

Conclusions of literature review:

1. Type II Endoleaks are frequently occurring 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 aims to come to a successful, 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 6Fr introduction sheath 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 for visibility during the injection procedure, which will make the EVAR invisible for future imaging when necessary.

## **Contacts**

### **Public**

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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; AND
- Possibility to withhold anti-thrombotic 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
- Women of child bearing potential: 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: Recruitment stopped

Start date (anticipated): 17-05-2018

Enrollment: 5

Type: Actual

### Medical products/devices used

Generic name: Aneufix; more specifically the model ACP-T5; which is a 2-component polymer that cures rapidly and non

Registration: No

## Ethics review

Approved WMO

Date: 20-12-2017

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Not approved

Date: 01-03-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
metc-ldd@lumc.nl

Approved WMO

Date: 18-08-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)  
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## 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

**Register**

CCMO

**ID**

NL63776.098.17