Abdominal Aortic Aneurysm Sac Healing and Prevention of Endoleaks - A Prospective Multicenter Study.

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To evaluate the safety of IMPEDE-FX Embolization Plug and/or IMPEDE-FX RapidFill to fill a AAA sac outside of an EVAR stent graft, and the efficacy of the IMPEDE-FX Embolization Plugs to reduce the volume and/or diameter of the AAA sac and/or the…

Ethical review	Approved WMO
Status	Completed
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON54411

Source
ToetsingOnline

Brief title
AAA-SHAPE_NLD

Condition

- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
abdominal aortic aneurysm; abdominal aortic widening

Research involving
Human

Sponsors and support

Primary sponsor: Shape Memory Medical
Source(s) of monetary or material Support: Shape Memory Medical

Intervention

Keyword: abdominal aortic aneurysm, embolization, endoleak, endovascular aneurysm repair

Outcome measures

Primary outcome

Primary endpoints are:

• Incidence of related major adverse events (MAEs*), from the day of procedure through 30 days post-procedure. Relatedness to the investigational product/procedure to be adjudicated by the independent safety monitor.

• Rate of technical success, defined as filling of the residual flow lumen of the AAA sac with investigational products, based on pre-procedure CTA and intra-procedural contrast-angiography of the residual blood lumen (*lumenogram*).

Secondary outcome

Other endpoints include the rate of adverse events through 5 years, the rates of endoleaks and other EVAR-related complications, and changes in sac size (diameter and volume) through 5 years.

Study description

Background summary

An abdominal aortic aneurysm (AAA) is an enlarged area in the lower aorta. Over time, this enlargement can become weak and the force of normal blood pressure can cause it to expand and rupture. This can lead to haemorrhage and death. Endovascular aneurysm repair (EVAR) is a standard of care procedure to treat AAAs. Complications of EVAR include endoleaks. Endoleak is defined as persistent blood flow in the aneurysm sac (the area outside the stent graft) after EVAR. Furthermore, failure of a AAA sac to decrease in size after EVAR

has been linked to shorter long-term survival.
It has been shown that filling the AAA sac with material, including embolic material, contributes to a reduction in the number of endoleaks and consequent reinterventions, and a stabilization/decrease in the size of the AAA sac.
The shape memory polymer in the investigational product is a porous embolic scaffold and may contribute to a reduction in the number of endoleaks and consequent reinterventions, and a stabilization/decrease in the size of the AAA sac. This polymer is already clinically applied for embolization of peripheral vasculature. The purpose of this study is to evaluate the IMPEDE-FX Embolization Plug and/ or IMPEDE-FX RapidFill for filling the AAA-sac outside of the EVAR-stent graft.

Study objective

To evaluate the safety of IMPEDE-FX Embolization Plug and/or IMPEDE-FX RapidFill to fill a AAA sac outside of an EVAR stent graft, and the efficacy of the IMPEDE-FX Embolization Plugs to reduce the volume and/or diameter of the AAA sac and/or the rate of other post-EVAR complications.

Study design

A prospective, multicenter, single-arm, open-label, post-market interventional clinical investigation with marketed medical devices being investigated for a new indication.

Intervention

The application of the embolization plug to reduce the volume and/or diameter of the AAA sac post-EVAR.

Study burden and risks

The study procedure is performed immediately following elective standard of care EVAR (in the same procedure). Baseline assessments are in line with standard of care EVAR. An additional tube of blood may be drawn, depending on study site standard of care for blood tests prior to EVAR. Preparation for the procedure is in line with standard of care EVAR. The process of filling the sac with investigational product after the EVAR stent graft is in place extends the procedure by as much time is necessary to insert the devices into the AAA sac. The amount of extra time needed is estimated to be approximately 25 min.
The follow-up regimen is similar to standard of care for EVAR: study participants are required to attend study follow-up visits at 30 days, 6 months, 1 year, and 2-5 years. Computed tomography (CT)-based imaging and ultrasound imaging and a blood draw (through 6 months) will occur at these visits. Depending on study site standard of care follow-up for EVAR, the study participant may undergo an additional CT scan at 6 months and 2-5 years for the

study. Again, depending on study site standard of care follow-up for EVAR, the ultrasound scan at 30 days and 1-5 year may be in addition to standard of care. The types of risks associated with the procedure are similar to those for standard of care EVAR and literature reports of AAA sac filling. The potential benefits are that the AAA sac filling reduces the volume and/or diameter of the AAA sac and/or the rate of endoleaks and other post-EVAR complications.

Contacts

Public
Shape Memory Medical

Aldo Avenue, Suite 109 807
Santa Clara CA 95054
US
Scientific
Shape Memory Medical

Aldo Avenue, Suite 109 807
Santa Clara CA 95054
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. >=18 years of age.
2. A candidate for elective EVAR of an infrarenal aortic aneurysm >=5.5 cm in diameter in men and >=5.0 cm in women.

Exclusion criteria

1. An inability to provide informed consent.
2. Enrolled in another clinical study.
3. Aortoiliac aneurysm, or concomitant iliac artery ectasia or aneurysm (common iliac artery diameter >24 mm) close to the bifurcation and/or that cannot be adequately sealed.
4. Patent AAA sac feeding vessels (within the sac) >4 mm in diameter.
5. Volume of AAA sac to be filled after stent graft placement <20 mL or >135 mL, based on pre-procedure CTA (i.e., aortic flow volume exclusive of stent graft volume).
6. Use of aortic stent grafts other than the Gore Excluder AAA Endoprosthesis, Cook Zenith Flex AAA Endovascular Graft, or Medtronic Endurant II Stent Graft to treat the AAA.
7. Planned use of the chosen stent graft outside its instructions for use (IFU).
8. Planned use of fenestrated or chimney stent grafts.
9. Study participants in which stent graft placement is abandoned for any reason, and/or in which the investigator decides, during the course of the stent graft placement, that the study procedure may not be appropriate.
10. Planned use of embolic devices other than the investigational product to embolize the AAA sac.
11. Vascular disease and/or anatomy that preclude the safe access and positioning of a catheter to deliver the investigational product into the AAA sac.
12. Ruptured, leaking, or mycotic (infected) aneurysm.
13. Aneurysmal disease of the descending thoracic aorta.
14. Coagulopathy or uncontrolled bleeding disorder.
15. Long-term (>6 months prior to the procedure) use of direct oral anticoagulant or any vitamin K antagonist anticoagulant use.
16. Serum creatinine level >2.5 mg/dL.
17. Cerebrovascular accident within 3 months prior to the procedure.
18. Myocardial infarction and/or major heart surgery within 3 months prior to the procedure.
19. Atrial fibrillation that is not well rate controlled.
20. Unable or unwilling to comply with study follow-up requirements.
21. Life expectancy of <2 years post-procedure.
22. Known hypersensitivity or contraindication to platinum, iridium, or polyurethane.
23. A condition that inhibits radiographic visualization during the implantation procedure.
24. History of allergy to contrast medium that cannot be managed medically.
25. Uncontrolled co-morbid medical condition, including mental health issues, that would adversely affect participation in the study.
26. Pregnant or a lactating female. For females of child-bearing potential, based on a positive pregnancy test within 7 days prior to the procedure or refusal to use a medically accepted method of birth control for the duration of

the study.
27. Member of a vulnerable population.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-08-2021
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	IMPEDE-FX Embolization Plug and IMPEDE-FX RapidFill
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-04-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	19-09-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT04751578
CCMO	NL76926.091.21