Aorfix* Bifurcated Safety and Performance Trial Phase II: Angulated Vessels -- A Study to assess the acute technical success of Aorfix* Stent Grafts in the treatment of Abdominal Aortic and Aorto-Iliac Aneurysm where a significant degree of vessel angulation exists at the neck of the aneurysm or in the common iliac arteries.

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To assess the safety and performance of Aorfix* Stent Graft in the treatment of Abdominal Aortic and Aorto-Iliac Aneurysm where a significant degree of vessel angulation exists at the neck of the aneurysm or in the common iliac arteries.

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

Summary

ID

NL-OMON31811

Source
ToetsingOnline

Brief title
ARBITER 2: Aorfix Safety and Performance Trial: angulated vessels

Condition

- Aneurysms and artery dissections

Synonym
Abdominal aortic aneurysm or, aortic dilatation., in layman terms

Research involving
Human

Sponsors and support

Primary sponsor: Anson Medical Ltd.; t/a Lombard Medical Cardiovascular Devices Division
Source(s) of monetary or material Support: the study sponsor: Lombard Medical PLC

Intervention

Keyword: Abdominal Aortic Aneurysm, Endovascular intervention, Stent Graft

Outcome measures

Primary outcome

The primary endpoints are acute technical success, initial performance and safety at 1-month follow up. Technical success is defined as successful passage of delivery system to the landing zone accurate placement of the device at the target zone, accurate positioning of the contra-lateral limb and withdrawal of the delivery system post deployment. Performance is defined as aneurysmal exclusion and flow restoration as evidenced by freedom from acute endoleak. Safety is defined as the absence of clinical complications during and after the clinical procedure (up top 1-month post-procedure).

Secondary outcome

Secondary endpoints will examine recovery factors: operative time, ICU duration, blood loss, days to normal diet, days to discharge, days to ambulation, freedom from non-clinical events, need for secondary procedure and

conversion to uni-iliac. Also safety at 6-month follow-up as measured by

serious adverse events that occur up to 6-months post-procedure.

Study description

Background summary

ARBITER-II: Aorfix* Bifurcated Safety and Performance Trial: Phase II, Angulated Vessels.

The most common treatment for AAAs is invasive open abdominal surgery. Early in the last decade a less invasive technique (endovascular stent grafting) was developed, beneficial to non-surgical AAA candidates. The Aorfix* has been designed by surgeons and engineers with the treatment of challenging cases in mind. Owing to this device*s unique design, it is hoped that the device will help to overcome some of the potential complications that exist with current endovascular stent grafts, such as device malpositioning, device migration or incomplete device deployment.

Study objective

To assess the safety and performance of Aorfix* Stent Graft in the treatment of Abdominal Aortic and Aorto-Iliac Aneurysm where a significant degree of vessel angulation exists at the neck of the aneurysm or in the common iliac arteries.

Study design

The investigation is a prospective open label, single arm, multi-centre clinical study designed to assess the safety and performance of the Aorfix* stent graft.

Intervention

Endovascular repair of an abdominal aortic aneurysm is an minimally interventional procedure that will allow aneurysm exclusion using a stent graft passed inside the aorta either percutaneously or from a small groin incision.

Study burden and risks

The potential adverse effects, risks or hazards for research participants are expected to be similar to those associated to treatment with other stent grafts. Endovascular grafting is a less invasive procedure than open surgery,

involving less cutting and may result in smaller scars. This procedure may enable the patient to leave the hospital sooner and recover more quickly, with less pain and possibly reduced short term risks of complications and death than traditional surgery. Additionally, the use of Aorfix* may enable fewer complications associated with other endovascular stent grafts, such as device malposition, migration or incomplete device deployment to enable a more successful procedure. Successful treatment of the aneurysm with Aorfix* may also result in a high likelihood of the patient returning to normal life.
Recently an important trial has suggested that in certain specific cases of treating AAA, endovascular intervention is superior to traditional surgery.

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. Diagnosis of abdominal aortic aneurysm 50 mm or larger in diameter, 40 mm or larger in diameter if symptomatic (i.e. pain, embolisation), or documented AAA growth of more than 5 mm within the previous 6 months, and/or including extension into common iliac artery(ies), or any saccular aneurysm.
2. Infrarenal neck with a minimum length of 15 mm and a neck angulation between 60° and 90°, as assessed in 3 dimensions.
3. The iliac artery diameter must be of appropriate diameter (1 mm smaller than the device diameter), with an appropriate distal landing length. The tortuosity of the common or external iliac arteries or femoral arteries must be low to medium (refer to operations manual).
4. Patient provides written informed consent.
5. Patients >18 years who are suitable for endovascular repair.
6. Patient fit for endovascular surgery, with a diameter at the access sites of 7mm or larger bilaterally.
7. Patient has a life expectancy longer than the duration of the study.

Exclusion criteria

1. Patient has a ruptured aneurysm.
2. Patient has insufficient length of proximal aneurysm neck (<15mm from aneurysm to lowest renal artery and <20 mm from the aneurysm to the SMA).
3. Aneurysm extends above renal arteries.
4. Proximal neck of aneurysm has significant loose thrombus associated with it, or significant circumferential calcifications.
5. Pregnant or nursing patients.
6. Patient unfit for bail-out surgery and appropriate anaesthesia.
7. Patient with an acute or chronic aortic dissection or mycotic aneurysm (defined by localised asymmetric aneurysm sac).
8. Patient has current non-localised infection.
9. Patient has known allergy to graft materials, Nitinol, or contrast media.
10. Patient*s where imaging is problematic; an example is an obese patient.
11. Patient has co-morbidities that deny vascular access, including small / tortuous access vessels.
12. Patient has highly calcified and tortuous proximal necks or distal landing zones or iliac arteries.
13. Patient has renal failure (serum creatinine >2mg/dL or >176 mmol/l).
14. Patient has connective tissue disease (e.g. Marfan syndrome, Ehlers-Danlos syndrome).
15. Patient has a bleeding diathesis or dyscrasia.
16. Patient is not willing to comply with the follow up sequence, or his geographic location does not allow appropriate follow up.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2006
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	Aorfix stent graft
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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
CCMO	NL15252.028.06