ShOrt neCK AAA RAndomized Trial - ESAR and FEVAR: SOCRATES Physician-Initiated Trial Investigating ESAR (EVAR Plus Heli-FX EndoAnchors) and FEVAR for the Treatment of Aortic Aneurysms With Short Infrarenal Aortic Neck

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

Summary

ID

NL-OMON57472

Source
ToetsingOnline

Brief title
SOCRATES

Condition

- Aneurysms and artery dissections

Synonym
abdominal aortic aneurysma - local expansion of the abdominal aorta

Research involving
Human

Sponsors and support

Primary sponsor: Foundation for Cardiovascular Research and Education (FRCE)
Source(s) of monetary or material Support: FCRE,Medtronic B.V.

Intervention

Keyword: Abdominal Aortic Aneurysm, Cardiovascular Diseases, Endograft

Outcome measures

Primary outcome

1. Effectiveness endpoint:

Composite of technical success at index procedure, and freedom from type IA or type III endoleak, freedom from aneurysm related mortality (ARM), and freedom from secondary reinterventions through 12 months post index procedure.

2. Safety endpoint:

Freedom from MAE through 30 days post index procedure.

MAE defined as: All-Cause-Mortality, Bowel Ischemia, Myocardial Infraction, Procedural Blood Loss > 1000cc, Access related complications, permanent paraplegia and paraparesis at 30 days, disabling stroke, respiratory failure, or renal complications

Secondary outcome

1. Total contrast volume (ml) at index procedure

2. Total fluoroscopy time (minutes) at index procedure

3. Duration (minutes) of index procedure (time between initial skin

access to final closure of the last artery access site)

4. Superiority of primary safety endpoint

5. Superiority of primary effectiveness endpoint

6. Adequate penetration of endo anchors as accessed by the Core Lab

7. Clinical success defined as technical success + freedom from intraoperative death and freedom from type IA/III endoleak in the first post-op image within 30 days.

8. Visceral artery patency or occlusion at 1-, 12-, 24- and 36-months follow-up

9. Freedom from type Ia and III endoleaks at 1-, 12-, 24- and 36-months follow-up

10. Freedom from aneurysm related secondary reinterventions at 1-, 12-, 24- and 36-months follow-up

11. Freedom from aneurysm related mortality at 1-, 12-, 24- and 36-months follow-up

12. Freedom from stent graft migration (>10mm change from 1-month follow-up imaging) at 12-, 24- and 36-months follow-up

13. Sac dynamics (>5mm change from 1-month follow-up imaging): increase, stable, decrease at 12-, 24-, and 36-months follow-up

14. Freedom from conversion to open repair at 1-, 12-, 24- and 36-months follow-up

15. Freedom from AAA rupture at 1-, 12-, 24- and 36-months follow-up

16. Overall SCI rate, include transient events at 1- and 12-months followup

Study description

Background summary

Abdominal aortic aneurysms (AAA) with a short and hostile infrarenal neck present higher risk independently from the technique used to treat them. The morbidity and mortality after open surgery is high, especially in multimorbid subjects (13, 14). Suprarenal or supravisceral clamping increased the risk of renal function deterioration and cardiac failure.
Over the years, many different techniques have been used to manage AAA with hostile proximal neck, including FEVAR (Fenestrated endovascular aortic repair) and ESAR (endosuture aortic repair). However, for FEVAR renal catheterization and stenting are required, and the procedure is technically demanding with high radiation exposure and contrast media use. Additionally, FEVAR procedures require custom made devices which increases case planning complexity and are technically demanding. The postoperative mortality is low, but during the follow up there is a risk of loss of target vessel patency with consequent renal or mesenteric ischemia. ESAR consisting of standard EVAR in combination with EndoAnchors evolved as an endovascular alternative to open surgery or FEVAR for aneurysm with short and hostile necks. The rationale of this method is to improve fixation of the endograft using the Heli-FX EndoAnchor System. Mimicking the security of a hand-sewn aortic anastomosis, EndoAnchors are intended to provide fixation and sealing between endovascular grafts and the native aortic wall at the level of the proximal attachment site, with good assistance in the prevention and management of type Ia endoleaks and stent-graft migration in patients with challenging aortic necks. Compared to FEVAR, ESAR does not require devices customized to a specific subject's anatomy and is a less technically demanding procedure reducing radiation exposure and contrast medium load. Additionally, the technique does not require cannuation and stenting of the renal and visceral arteries. This technique is technically easier and can be adopted also by centers not familiar with renal artery catheterization and stenting. The risk of stent-related complications (thrombosis, instent restenosis, fractures, secondary procedures) is also lower.

Studies showed that the Endurant II/IIs endograft in conjunction with Heli-FX EndoAnchor implants appear to be a safe and effective treatment option with procedural success rate of 97.1% and technical success rate of 88.6%.
However, to date, there is no head-to-head comparison between the FEVAR and the ESAR treatment options for AAA with short and hostile infrarenal necks.

Study objective

The aim of this randomized study is to compare the safety and performance of EndoVascular Aneurysm Repair with ESAR using Endurant + Heli-FX EndoAnchor and FEVAR using customizable grafts from Cook (Zenith Fenestrated Graft) and Terumo

(Fenestrated Anaconda Graft) for the treatment of aortic aneurysms with short aortic neck (4 to 15mm). Both techniques and medical devices are currently being used as standard of care in the treatment of abdominal aortic aneurysm.

Study design

Investigator-initiated, prospective, interventional, multi-center, randomized (1:1), two-arm, open-label, non-inferiority postmarket study

Intervention

The study will enroll at least 204 subjects randomized 1:1 to ESAR or FEVAR procedure .

This study will utilize the CE marked/PMA approved Medtronic Endurant II/IIs Stent Graft Systems in combination with Medtronic Heli-FX EndoAnchor system for the ESAR procedures. For FEVAR procedures, this study will utilize CE marked/PMA approved and/or custom made commercially available Cook Zenith Fenestrated or Terumo Fenestrated Anaconda stent graft systems. All devices will be used within intended use as described in the approved Instructions for Use (IFU) for which CE mark/PMA approval has been obtained.

Group 1: ESAR procedure: Endovascular Aneurysm Repair (endograft) + Heli-FX EndoAnchors
Medical devices used: Medtronic Endurant II and Endurant IIs Stent Graft Systems with Heli-FX EndoAnchor system

Group 2: FEVAR procedure: Fenestrated EndoVascular Aneurysm Repair (fenestrated endograft)
Medical devices used: Cook Zenith Fenestrated of Terumo Fenestrated Anaconda stent graft systems

A more detailed description of both techniques used:
Endovascular aortic repair (EVAR) is a minimally invasive procedure by using a stent to repair aortic aneurysms and dissections that occur in the abdominal aorta. The fenestrated endograft is inserted into the femoral artery via an incision in the groin percutaneously, or through the skin. It is then guided through the blood vessel to the aneurysm. Advantages of endovascular treatment of complex aneurysmas are: less invasive surgery, shorter hospitalization time and less scar tissue. Disadvantages are: annual control visits and use of radiation and contrast medium.

FEVAR technique: Traditional EVAR works when aneurysms are located far enough from the renal (kidney) arteries, which branch off the aorta, that the stent can be securely attached to the aorta. However, for approximately 10 percent of patients with an abdominal aortic aneurysm, the aneurysm is too close to the

arteries that branch off to the kidneys for traditional EVAR to work. The location of this aneurysm is complicated to treat and often requires open surgery to repair the weakened wall. Until recently, the only option these patients had was major abdominal surgery or no surgery at all. The unique feature of fenestrated endografts (FEVAR) is that they can cover branch arteries of the aorta (such as the renal arteries) because the graft has fenestrations, or holes, that correspond to the position of the branching arteries within the aorta to allow for blood to flow through the graft into the branch vessel. This FEVAR procedure will be applied in one of the 2 study groups. FEVAR procedures often require custom made devices and are technically demanding. the production takes 8-12 weeks. In some cases its remains impossible to produce a stent that fits due to anatomical or technical reasons.

ESAR technique: ESAR uses standard (non-fenestrated) endografts or stents in combination with a Heli-FX* EndoAnchor* system from Medtronic, which improve fixation of the endograft to the aortic wall thereby reducing the risk f stent migrationand endoleaks. This technique will be applied in the other study group.

Study burden and risks

Patients will be randomized to a 'standard of care' treatment (FEVAR or ESAR) and will undergo the same treatment as those who does not participate in this study. After 1, 12, 24 and 36 months a CT angiography will be performed to follow up the result of the procedure which is not different from the follow-up protocol of patients undergoing ESAR or FEVAR not participating in this trial. As such, the patient will not be exposed to additional radiation by participating in this trial. For patients with renal insufficiency during follow-up who should not be given contrast medium will have an MRI or a CT without contrast with duplex ultrasound imaging, in order to monitor the stent and the aneurysm.

The risks listed below are thus inherent to the 'standard of care' treatment for this patient population.
During ESAR or FEVAR procedures a vessel or the aorta can be injured (perforation or dissection), or embolization can occur. Based on the literature, these findings occur in <1% of subjects. During FEVAR procedure, occlusion of the BSG (Bridging Stent Graft) can lead to organ ischemia, which can lead to death in a worst-case scenario. During FEVAR, occlusion of the renal artery can lead to renal function impairment and dialysis if left untreated.
In both ESAR and FEVAR procedures, endoleaks could lead to aneurysm sac enlargement and eventually rupture. These are expected to be found in <3% of subjects and should be treated accordingly to avoid further sac enlargement.

The use of both ESAR and FEVAR procedures is a safe and effective technique. All study products are CE marked/PMA approved and/or custom made and will be

used according to their applicable IFUs. Furthermore, the indications and contraindications are provided in the instructions for use of the respective devices. For a complete list of possible risks we refer to the IFU of the medical devices used in the trials:

ESAR procedure: Medtronic Endurant II/IIs Stent Graft Systems in combination with Medtronic Heli-FX EndoAnchor system
FEVAR procedure: Cook Zenith Fenestrated or Terumo Fenestrated Anaconda stent graft systems

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

General inclusion criteria:

- Subject is >18 years old
- Subjects is scheduled for primary treatment of the abdominal aortic aneurysm with a non-aneurysmal infrarenal aortic sealing zone proximal to the aneurysm that is sufficiently healthy for a proximal neck length that is at least 4 mm and not more than 15 mm and has a circumferential minimum sealing zone length of 8 mm
- Subject is not a candidate for safe, effective and durable standard EVAR due to challenging anatomical criteria as confirmed by the core lab screening committee
- Subject is able and willing to comply with the protocol and to adhere to the follow-up requirements.
- Subject has provided written informed consent
- Subject meets the other anatomical requirements according to the locally applicable Endurant II/IIs stent graft system, Heli-FX EndoAnchor system, Terumo Fenestrated Anaconda (available in EU only) and/or Cook Zenith Fenestrated Graft Instructions for Use

CT Angiography Inclusion Criteria:
- Proximal neck length of the aorta within 4-15mm and minimum circumferential sealing zone of 8mm
- Infrarenal neck angulation less than or equal to 45 degrees
- Aortic neck diameter between 19 and 31mm

Exclusion criteria

- Subject is participating in a concurrent study which may confound study results
- Subject has a life expectancy <2 year
- Subject is a female of childbearing potential in whom pregnancy cannot be excluded
- Subject with an eGFR <30 mL/min/m2 (KDOQI classification exclude class IV and above) and/or on dialysis
- Subject with an MI or CVA within 3 months prior to index procedure
- Subject with known Connective Tissue Disease
- Subject has a known hypersensitivity or contraindication to anticoagulants, antiplatelets, or contrast media, which is not amenable to post-treatment.
- Subject who has undergone prior endovascular or open surgical treatment for abdominal aortic aneurysm
- Subject requires emergent aneurysm treatment, for example, trauma or rupture
- Subject has a known hypersensitivity or allergies to study device implant material
- Subject has an aneurysm that is:
Suprarenal, pararenal, or thoracoabdominal
Mycotic
Inflammatory

Pseudoaneurysm
- Subject is presenting with thrombus or calcification of the proximal sealing zone: circumferential >50%
- Pre-operative stenosis of the renal arterial >50%
- Subject has active infection or history of COVID-19. History of COVID-19 is defined as availability of positive COVID-19 test with sequelae or hospitalization for treatment of COVID-19.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2023
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Endurant II/Endurant IIs bifurcated stent grafts / Heli-FX EndoAnchor System / Cook Zenith Fenestr
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-05-2025

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT04503395
CCMO	NL79933.100.23