Randomized controlled clinical trial on the application of Heli-FX EndoAnchors in conjunction with the Endurant II/IIs endograft in infrarenal aortic aneurysms with a wide infrarenal neck

Published: 02-05-2023
Last updated: 30-01-2025

The primary objective of this study is to investigate if the use of Heli-FX EndoAnchors in conjunction with placement of aortic stent grafts under instructions for use (IFU) conditions in aneurysms with a wide neck is superior to treatment with...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON53733

Source
ToetsingOnline

Brief title
HERCULES Trial

Condition

- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
bulge in the aorta; enlarged abdominal blood vessel

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Industry,Medtronic B.V.

Intervention

Keyword: abdominal aneurysm, EndoAnchors, endograft, wide neck

Outcome measures

Primary outcome

The primary endpoint is a composite based on core lab reported data from

computed tomography (CT) with contrast imaging of freedom from:

(1) type IA endoleak AND

(2) Migration of the proximal portion of the stent graft >=5 mm (compared to

1-month imaging) AND

(3) Aneurysm sac growth >=5 mm (compared to 1-month imaging).

Secondary outcome

The following secondary endpoints will be evaluated using core lab reported

data :

• Freedom from type IA endoleak

• Freedom from migration of the proximal portion of the stent graft >= 5 mm

(compared to 1-month imaging)

• Freedom from aneurysm growth >= 5 mm (compared to 1-month imaging)

• Freedom from neck dilatation >=3 mm

Study description

Background summary

After more than 25 years of Endovascular Aneurysm Repair (EVAR) researchers are still unraveling the factors that attribute to a more or less favorable outcome on the long-termoutcome after EVAR. Wide necks have been identified as one of the parameters of a hostile neck and are typically defined as a neck with a diameter of 28 mm or more. It was recently shown that the use standard EVAR requiring a 34- to 36-mm diameter endograft is independently associated with an increased rate of proximal fixation failure, which was a composite of type IA endoleak and stent graft migration >10 mm after EVAR. A recent review revealed that patients with a wide proximal aortic neck undergoing standard EVAR have a lower freedom from aneurysm-related reinterventions, type IA endoleak, sac expansion and aneurysm rupture. The authors concluded that a wide neck should be taken into consideration when establishing a treatment.
Heli-FX EndoAnchors have successfully been applied to resolve type IA endoleaks in patients with a hostile neck anatomy, but they have also been used to prevent endoleaks in patients with an aneurysm with a short infrarenal neck. In an analysis of the ANCHOR registry it was shown that the Endurant II/IIs endograft in conjunction with Heli-FX EndoAnchor implants (ESAR) is a safe and effective treatment option with a high technical success rate and low incidence of type IA endoleaks and secondary interventions. In addition, the use of Heli-FX EndoAnchors also appears to have a protective effect on neck dilatation, which is particularly relevant in patients with a wide neck. They have recently also been related to aneurysm shrinkage after EVAR, implying a better seal.
This study is being conducted to collect clinical evidence from treatment of patients with infrarenal Infrarenal abdominal aortic aneurysm (AAA) having wide proximal aortic neck diameters (>= 28mm and <= 32mm), comparing clinical outcomes with treatment of the AAA with the Endurant II/IIs stent graft in conjunction with Heli-FX EndoAnchors to treatment of the AAA with the Endurant II/IIs stent graft alone. Though both the Endurant II/IIs stent graft and Heli-FX EndoAnchors are commercially approved in this indication, clinical evidence comparing these two treatments in patients with wide proximal aortic neck diameters is not currently available. Collecting clinical data specific to this patient population, including procedure and imaging data as well as long term outcomes, will provide a foundation to further characterize the clinical outcomes of treatment for patients with infrarenal AAA with wide proximal aortic neck diameters.

Study objective

The primary objective of this study is to investigate if the use of Heli-FX EndoAnchors in conjunction with placement of aortic stent grafts under instructions for use (IFU) conditions in aneurysms with a wide neck is superior to treatment with stent grafts alone in regards to proximal seal outcomes.

The secondary objective of this study is to investigate if the use of Heli-FX EndoAnchors in aneurysms with a wide neck reduces the occurrence of Type IA endoleak, migration, aneurysm sac growth, and neck dilatation and if Heli-FX

EndoAnchors positively affect aneurysm remodelling in patients with a wide infrarenal neck.

Study design

HERCULES is a post-market, prospective, global, multicenter, randomized (1:1), two-arm, superiority trial designed to compare ESAR to standard EVAR clinical outcomes in treatment of infrarenal AAA in patients having wide proximal aortic neck diameters (>= 28 mm and <= 32 mm).
All subjects shall be followed per local societal guidelines and per the Endurant II/IIs and Heli-FX EndoAnchor instruction for use (IFU) recommendations for post-implant follow-up and CT-imaging, with expected assessments at baseline, index procedure(s), 1-month, and annually at 1, 2, 3, 4, and 5 years post-index procedure.

Study burden and risks

Any surgical procedure poses a potential risk. The procedures undertaken as part of this study are no exception. There are known risks associated with the use of anaesthesia and risks associated with a surgical procedure involving a device. The risks, adverse events and complications associated with the study devices are clearly identified in the Instructions for Use (IFUs), which are inlcuded in the submission package.
As such, risks associated with endovascular device implant procedures are identical to procedures undertaken as part of standard care treatments; all patients to be included are eligible for either one of the treatment arms, so no additional risks exist in regards to the procedural implant procedure.
Regular CT-scans with contrast are required at follow-up visits. In certain cases, these CT-scans are not standard of care and could potentially be an additional risk to the patients. Howver, as detailed in the document "Radiation Dose Justiification Hercules trial_16Feb2023" signed J. Simmering (and included in the submission), the radiation exposure dose falls in risk category IIa which is an acceptable risk when it *increases in knowledge leading to health benefit".

.

Contacts

Public
Rijnstate Ziekenhuis

Wagnerlaan 55

Arnhem 6815 AD
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Age 18 years or older
• Provided written informed consent
• Clinical necessity for treatment of the AAA, according to the current guidelines in the geographies participating
• Elective repair
• Eligible anatomy for treatment with the Endurant II/IIs endograft and Heli-FX EndoAnchors according to the IFU of both devices
• Infrarenal neck diameter >= 28 mm and <=32 mm
• Proximal neck length >=10mm

Exclusion criteria

• Anatomy outside the IFU of the Endurant II/IIs endograft and/or Heli-FX EndoAnchors
• Planned use of AUI main body device
• Patient is participating in another clinical study, potentially conflicting with the outcomes of the current study.
• Patient with eGFR < 30 ml/min/1.73m2 before the intervention
• Patient*s life expectancy <2 years as judged by the investigator

• Patient has a psychiatric or other condition that may interfere with the study
• Patient has a known allergy to any device component
• Patients with a systemic infection who may be at increased risk of endovascular graft infection.
• Patient has a coagulopathy or uncontrolled bleeding disorder
• Patient has a ruptured, leaking, or mycotic aneurysm
• Patient is not eligible for standard EVAR
• Patient had a Cerebro Vascular Accident (CVA) or a myocardial infarction (MI) within the prior three months
• Patient is pregnant (Female patients of childbearing potential only)
• Patient has active COVID-19 infection or has been diagnosed with long COVID-19 requiring hospitalization within the 6 months prior to procedure.
• Patient has previously been treated with stent grafts in the aorto-iliac arteries

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2024
Enrollment:	28
Type:	Actual

Medical products/devices used

Generic name:	Endurant II/Endurant IIs stent graft system; Heli-FX EndoAnchor System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-05-2023
Application type:	First submission
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	NCT05484115
CCMO	NL82691.091.22