EndurAnt Stent Graft system vs ExcluDer endoprothesis: a global, prospectiVe, rANdomized Clinical trial in sac rEgression (ADVANCE Study)

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The purpose of this study is to generate clinical evidence related to key performance outcomes of Endurant II/IIs Stent Graft System versus Gore Excluder/Excluder Conformable AAA Endoprosthesis in subjects with AAA.

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

Summary

ID

NL-OMON51685

Source
ToetsingOnline

Brief title
ADVANCE study

Condition

- Aneurysms and artery dissections

Synonym
repair of abdominal aortic aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.

Source(s) of monetary or material Support: Medtronic Inc.

Intervention

Keyword: abdominal aortic aneurysm (AAA), Endovascular aneurysm repair (EVAR), EndurAnt Stent Graft system

Outcome measures

Primary outcome

The primary objective of this trial is to evaluate sac regression outcomes of the Medtronic Endurant II/IIs Stent Graft System and Gore Excluder/Excluder Conformable AAA Endoprosthesis in standard EVAR subjects.

The primary endpoint is defined as the proportion of subjects with sac regression at 1 year based on CT image as analyzed by Core Lab. Sac regression is defined in accordance with Society for Vascular Surgery (SVS) Guidelines as the reduction in maximum diameter of the aneurysm sac by >=5 mm when compared to the first CT imaging study obtained after index procedure.

Secondary outcome

A secondary objective of this trial is to investigate predictors of sac regression as well as stability and expansion. The trial evaluates whether sac dynamics predict late mortality and reinterventions. Analysis is also performed to evaluate the difference in sac diameter and volume between treatment groups.

To evaluate rates of pre-specified parameters allowing investigation of secondary objectives, the following endpoints are evaluated:

• Aneurysm sac change by diameter at 1-year and annually thereafter up to 5

years as compared to the first CT imaging after index procedure

• Aneurysm sac change by volume at 1-year and annually thereafter up to 5 years

as compared to the first CT imaging after index procedure

• Type II Endoleaks incidence comparison between treatment groups through

1-month, 1-year and annually thereafter up to 5 years

• Type I Endoleaks incidence comparison between treatment groups through

1-month, 1-year and annually thereafter up to 5 years

• Secondary Interventions incidence comparison between groups through 1-month,

1-year and annually thereafter up to 5 years

• All-Cause Mortality incidence comparison between groups through 1-month,

1-year and annually thereafter up to 5 years

Study description

Background summary

Pls see CIP section 4.1 page 18 to 22

Study objective

The purpose of this study is to generate clinical evidence related to key performance outcomes of Endurant II/IIs Stent Graft System versus Gore Excluder/Excluder Conformable AAA Endoprosthesis in subjects with AAA.

Study design

This study is designed as a post-market, prospective, interventional, nonblinded, global, multi-center, randomized (1:1), dual arm, study. The study is being conducted to collect clinical evidence of treatment of abdominal aortic aneurysm with Endurant II/IIs Stent Graft System compared to Gore Excluder/Excluder Conformable Endoprosthesis in subjects with AAA indicated for an EVAR procedure. CT imaging will be performed at every follow-up visit, which follows the long-term surveillance recommendations of the Instruction for Use (IFU). The study is expected to be conducted at up to 100 study sites located

in Europe, the United States, Japan and Taiwan. A estimate of 550 subjects will be enrolled in the study (minimum 500) with a potential to increase the sample size (upper limit of 900 subjects) based on predictive probability analysis to achieve superiority for the primary endpoint at pre-specified interim analyses for sample size evaluations. The expected duration of each subject*s participation is up to 5 years after the index procedure.

In accordance with EU MDR, the preceding investigation procedure in this study is defined as CT imaging with contrast during follow up visits up to 5 years.

Intervention

Subjects who meet the eligibility criteria and enroll will be followed for five years. Clinical data should be collected at baseline, index procedure, hospital discharge, 1-month, 1 year and annually through 5 years.
Additional imaging studies may be recommended at physician*s discretion in cases of specific events including but not limited to the presence of an endoleak or aneurysm sac enlargement. The sponsor will require submission of all follow-up imaging as well as any relevant additional imaging studies for analysis by the sponsor and/or independent Core Laboratory.
See for more information CIP section 10.1 Schedule of Events

Study burden and risks

EVAR is now established as having an acceptable safety profile and is considered an effective treatment option for subjects with symptomatic abdominal aortic aneurysms who are at low to extreme risk for open surgical repair of AAA.
Appropriate risk management activities have been performed for the Endurant II/IIs Stent Graft system and/or Gore Excluder/Excluder Conformable system resulting in a positive risk-to-benefit rationale given the products have received local regulatory body approval.

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

Inclusion Criteria:
Subjects must meet ALL of the following inclusion criteria:
1) Subject is >= 20 years old
2) Subject and the treating physician agree that the subject will return for all required follow-up visits
3) Subject or legal representative or consultee, as applicable, has consented for study participation and signed the Informed Consent approved by the sponsor and by the Ethics Committee/Institutional Review Board
4) Subject has an aneurysm diameter of
o >= 5 cm (if woman)
o >= 5.5 cm (if man)
5) Subject's AAA anatomy is appropriate for both Medtronic Endurant II/IIs Stent Graft System and Gore Excluder/Excluder Conformable AAA Endoprosthesis as per assessment of both treating physician and Core Lab in accordance with the overlapping commercially available IFUs per applicable region.

Exclusion criteria

Subjects are NOT eligible for trial participation if they meet ANY of the following exclusion criteria:
1. Subject is participating in an investigational drug or device study which may bias or interfere with the endpoints and follow-up of this trial
2. Subject has an estimated life expectancy of <= 3 years as judged by the

investigator
3. Subject has an aneurysm that is:
a) Suprarenal/pararenal/juxtarenal
b) Isolated ilio-femoral
c) Mycotic
d) Inflammatory
e) Pseudoaneurysm
f) Concomitant or prior dissection involving the abdominal aorta or iliac arteries
g) Ruptured
h) Symptomatic AAA
4. Subject has significant thrombus and / or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. Significant thrombus may be quantified as thrombus >= 2 mm in thickness and / or >= 25% of the vessel circumference in the intended seal zone of the aortic neck.
5. Subject requires emergent aneurysm treatment, for example, trauma or rupture
6. Subject with connective tissue disease that may have caused the aneurysm e.g., Marfan syndrome, Ehlers-Danlos, Loeys-Dietz syndrome
7. Subject has previously undergone surgical or endovascular treatment in the abdominal aorta or the iliac arteries for aneurysm or occlusive disease
8. Planned use of aorto-uni-iliac (AUI) main body device
9. Any planned additional device (apart from the main body, limb stent graft and extensions per assigned treatment per randomization) duringindex or staged procedure, (e.g., endostaple or anchor, Iliac branch endoprosthesis, embolization ,etc.)
10. Planned coverage of the internal iliac artery/arteries
11. Subject has an estimated glomerular filtration rate (eGFR) < 45 ml/min/1.73m² or subject is on dialysis
12. Subject has a systemic infection who may be at increased risk of endovascular graft infection, per investigator*s discretion
13. Subject has a psychiatric or other condition that may interfere with the trial, per investigator*s discretion
14. Subject is of childbearing potential in whom pregnancy cannot be excluded
15. Subject has a known hypersensitivity or contraindication to anticoagulants, anti-platelets, or contrast media, which is not amenable to pre-treatment
16. Subject belongs to a vulnerable population per investigator's judgment
17. Subject has an active COVID-19 infection or relevant history 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:	Recruiting
Start date (anticipated):	06-06-2023
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Medtronic EndurantTM II/IIs Stent Graft System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-02-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-05-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCT05378347
CCMO	NL81693.078.22