Endurant Evo International Clinical Trial

Published: 02-04-2015
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The purpose of the Endurant Evo International Clinical Trial is to evaluate the safety and effectiveness of the Endurant Evo AAA Stent graft system for endovascular treatment of subjects with infrarenal abdominal aortic or aortoiliac aneurysms.

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

Summary

ID

NL-OMON47483

Source
ToetsingOnline

Brief title
EEVO

Condition

- Aneurysms and artery dissections

Synonym
Enlargement of the abdominal aorta

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Abdominal, aneurysm, graft, stent

Outcome measures

Primary outcome

Primary safety endpoint:

The primary safety endpoint is defined as the proportion of subjects experiencing an MAE within 30 days post-implantation. MAEs include the occurrence of any of the following events:

* All-cause mortality
* Bowel ischemia
* Myocardial infarction
* Paraplegia
* Procedural blood loss *1000 cc
* Renal failure
* Respiratory failure
* Stroke

Primary effectiveness endpoint:

Technical success at the index procedure (as assessed intra-operatively) is defined as successful delivery and deployment of the Endurant Evo AAA stent graft system in the planned location and with no unintentional coverage of both internal iliac arteries or any visceral aortic branches and with successful removal of the delivery system.

Secondary outcome

The following secondary endpoints will be evaluated:

* All cause-mortality within 30, 183, and 365 days

* Aneurysm-related mortality within 30, 183, and 365 days

* Secondary procedures to correct Type I and III endoleaks within 30 183 and 365 days

* Secondary endovascular procedures within 30, 183 and 365 days

* Serious adverse events within 30, 183 and 365 days

* Aneurysm rupture within 30, 183 and 365 days

* Conversion to open surgery within 30, 183 and 365 days

* Major adverse events within 183 and 365 days

* Stent graft migration at 12-month follow-up visit (as compared to 1-month imaging)

* Aneurysm expansion > 5 mm at 12-month follow-up visit (as compared to 1-month imaging).

* All endoleaks based on imaging findings at 1- month, 6-month and 12-month visits.

* Stent graft occlusion based on imaging findings through 6 months and 12 months.

* Device deficiencies based on imaging findings through 6 months and 12- months.

Secondary endpoints will be assessed at annual follow-up visits until 5 years post-implantation.

Study description

Background summary

Abdominal aortic aneurysms (AAA) occur in approximately 5% of the general population as estimated by a systematic literature survey of 56 epidemiological studies.The prevalence is greater in males compared with females and aneurysms are found more frequently in western countries than in Asia. Risk factors for AAA include advanced age, smoking, family history of AAA, hypertension, atherosclerosis, and hyperlipidemia. The female gender and diabetes were associated with a lower prevalence of AAA.
Aneurysms are prophylactically treated to prevent premature death from rupture. More than one-third of patients with ruptured aneurysms succumb from the event; a proportion that has not decreased appreciably over the last several decades. By contrast, elective treatment of AAA prior to rupture is associated with a perioperative mortality rate below 3%. For this reason, AAA are best managed electively, prior to rupture.
There are two general methods for repair of an AAA; traditional open surgical repair and endovascular repair. Traditional open surgical repair has been the standard technique for over six decades. Open repair is performed through a transperitoneal or retroperitoneal incision; sewing a prosthetic graft to the aorta above and below the aneurysm. While durable, open repair is associated with a significant risk of perioperative complications. The risk is particularly high in the elderly and in those with multiple medical comorbidities; the population who characteristically develop AAA.
Endovascular aneurysm repair (EVAR) is the second general technique for aneurysm repair. The objective of EVAR is to repair the aneurysm through the trans-vascular insertion of an endograft. EVAR has been shown to reduce 30-day and in-hospital mortality, blood transfusions, mechanical ventilation, and ICU and hospital length of stay compared to open surgery. Current endografts, while much improved over earlier devices, still suffer from some shortcomings.
Medtronic*s next generation AAA stent graft system on the Endurant product platform is the EndurantTM Evo Abdominal Aortic Aneurysm (AAA) stent graft system. The Endurant Evo AAA stent graft system was designed to further expand EVAR applicability and improve access in patients with challenging anatomies.

Study objective

The purpose of the Endurant Evo International Clinical Trial is to evaluate the safety and effectiveness of the Endurant Evo AAA Stent graft system for endovascular treatment of subjects with infrarenal abdominal aortic or aortoiliac aneurysms.

Study design

The Endurant Evo International Clinical Trial is a prospective, multi-center, pre-market, non-randomized, single-arm trial.

Intervention

Since the patient would have been treated with an AAA stent graft anyway, the intervention in this study is the use of the Endurant Evo stent graft, a fourth generation stent graft on the Endurant product platform of Medtronic.

Study burden and risks

Appendix L.3 of the CIP shows a list of potential adverse events that may be associated with use of the Endurant Evo AAA stent graft system. The occurrence of the listed complications may lead to a repeat endovascular intervention and/or open surgical repair. Since the Endurant Evo AAA stent graft system is an investigational device, all risks may not be known. However, they are believed to be similar to those associated with the existing endovascular devices in clinical use or commercially available, as well as the risks associated with standard open surgical repair of AAA. All efforts will be made to minimize these risks by selecting investigators who are experienced and skilled in using endovascular aortic devices and who have been adequately trained. Also, risk mitigation activities were performed during development and design verification tests of the device.
Other procedures within this study are part of the standard of care procedures associated with EVAR, except for the EQ-5D questionnaire which has to be completed by the subjects during the screening and FU visits.

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

- Subject is at least 18 years old
- Subject is a suitable candidate for elective surgical repair of AAA as evaluated by American Society of Anesthesiologists (ASA) Physical Status Classification System I, II, or III
- Subject has an infrarenal abdominal aortic or aortoiliac aneurysm characterized by one or more of the following:
a) Aneurysm is > 5 cm in diameter (diameter measured is perpendicular to the line of flow)
b) Aneurysm is 4 * 5 cm in diameter and has increased in size * 0.5 cm within the previous 6 months
- Subject meets all the following anatomical criteria as demonstrated on contrast-enhanced CT or MRA imaging:
a) Proximal neck length of * 10 mm with * 60° infrarenal and * 45° suprarenal neck angulation or Proximal neck length of * 15 mm with * 75° infrarenal and * 60° suprarenal neck angulation
b) Subject has vascular dimensions, e.g., aortic and iliac diameters, lengths from renal arteries to iliac bifurcation and hypogastric arteries, in the range of sizes available for the Endurant Evo AAA stent graft system (measured intima to intima) and within the sizing recommendations (refer to Endurant Evo AAA stent graft system Instructions for Use (IFU))
c) Subject has a proximal aortic neck diameter *18 mm and *32 mm
d) The distal fixation center of the iliac arteries must have a diameter *7 mm and * 25 mm bilaterally for the bifur and unilaterally for the AUI
e) Subject has documented imaging evidence of at least one patent iliac and one femoral artery, or can tolerate a vascular conduit that allows introduction of the Endurant Evo AAA stent graft system
f) Subject has distal non-aneurysmal iliac (cylindrical) fixation length * 20 mm bilaterally for the bifur and unilaterally for the AUI

Exclusion criteria

- Subject has a life expectancy * 1 year
- Subject has an aneurysm that is:
a. Suprarenal/ pararenal/ juxtarenal
b. Isolated ilio-femoral
c. Mycotic
d. Inflammatory
e. Pseudoaneurysm
f. Dissecting
g. Ruptured
h. Leaking but not ruptured
- Subject requires emergent aneurysm treatment
- Subject has a known, untreated thoracic aneurysm >4.5 cm in diameter at time of screening
- Subject has been previously treated for an abdominal aortic aneurysm
- Subject has a history of bleeding diathesis or coagulopathy
- Subject has had or plans to have an unrelated major surgical or interventional procedure within 1 month before or after implantation of the Endurant Evo AAA Stent Graft
- Subject has had a myocardial infarction (MI) or cerebral vascular accident (CVA) within 3 months prior to implantation of the Endurant Evo AAA Stent Graft
- Subject has a conical neck defined as a >4 mm distal increase from the lowest renal artery over a 10 mm length
- Subject has a known allergy or intolerance to the device materials
- Subject has a known hypersensitivity or contraindication to anticoagulants, antiplatelets, or contrast media, which is not amenable to pre-treatment
- Subject has significant aortic thrombus and/or calcification at either the proximal or distal attachment centers that would compromise fixation and seal of the device at the discretion of the investigator
- Subject has ectatic iliac arteries requiring bilateral exclusion of hypogastric blood flow
- Subject whose arterial access site is not anticipated to accommodate the diameter of the Endurant Evo AAA delivery system (13F-17F) due to vessel size, calcification, or tortuosity
- Subject is morbidly obese or has other documented clinical conditions that severely inhibit radiographic visualization of the aorta at the discretion of the investigator
- Subject has active infection at the time of the index procedure documented by e.g. pain, fever, drainage, positive culture and/or leukocytosis considered to be clinically significant per investigator discretion
- Subject has congenital degenerative collagen disease, e.g., Marfan*s Syndrome
- Subject has a creatinine level >2.00 mg/dl (or >176.8 µmol/L)
- Subject is on dialysis

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2015
Enrollment:	21
Type:	Actual

Medical products/devices used

Generic name:	Endurant EVO AAA stent graft system
Registration:	No

Ethics review

Approved WMO Date:	02-04-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-06-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-04-2017
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-10-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-12-2019
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
CCMO	NL52139.078.15