Valiant Evo International Clinical Trial

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The purpose of the Valiant Evo International Clinical Trial is to demonstrate the safety and effectiveness of the Valiant Evo Thoracic Stent Graft System in subjects with a descending thoracic aortic aneurysm (DTAA) who are candidates for...

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

Summary

ID

NL-OMON45800

Source
ToetsingOnline

Brief title
Valiant Evo

Condition

- Aneurysms and artery dissections

Synonym
Thoracic aortic aneurysm/ TAA / enlargement of the aorta in the chest

Research involving
Human

Sponsors and support

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

Intervention

Keyword: descending aorta, stentgraft, TEVAR, Thoracic aortic aneurysm (TAA)

Outcome measures

Primary outcome

Composite safety and effectiveness endpoint that is based on the proportion of subjects who experienced:

(a) Access and/or deployment failures; and/or

(b) Major device effect (MDE) within 30 days post index procedure

MDEs include the occurrence of any of the following and are defined in Appendix L.2.1:

• Device-related secondary procedures

• Device-related mortality

• Conversion to open surgery

• Thoracic aortic aneurysm rupture

An independent Clinical Events Committee (CEC) will be established to adjudicate MDEs.

Secondary outcome

30-day Secondary Endpoints:

The following secondary endpoints will be evaluated within 30 days post treatment:

· Peri-operative mortality

· All adverse events (AE) within 30 days including:

• Major Adverse Event(s) (MAE)

• Serious Adverse Event(s) (SAE)

· Secondary procedures

· Loss of stent graft patency at 30 day visit based on imaging findings

· Endoleaks at 30 day visit based on imaging findings

Major adverse events include the occurrence of any of the following:

· Respiratory complications: atelectasis, pneumonia, pulmonary embolism, pulmonary edema, respiratory failure

· Renal complications: renal failure, renal insufficiency

· Cardiac complications: Myocardial infarction (MI), unstable angina, new arrhythmia, exacerbation of congestive heart failure (CHF)

· Neurological complications: new cerebrovascular accident (CVA), cerebrovascular embolic events, paraplegia, paraparesis

· Gastrointestinal complications: bowel ischemia

· Major bleeding complication (procedural or post-procedural), coagulopathy

· Vascular complications: aortic rupture, hematoma at access site, pseudo or false aneurysm, arteriovenous (AV) fistula, retroperitoneal bleed, limb ischemia, thrombosis

12-month Secondary Endpoints:

The following secondary endpoints will be evaluated:

· All-cause mortality within 365 days

· Aneurysm-Related Mortality within 365 days

· MDEs within 365 days

· All AEs within 365 days including:

• MAEs

• SAEs

· Secondary procedures within 365 days

· Loss of stent graft patency within 12 months based on imaging findings

· Endoleaks at 12 months based on imaging findings

· Stent graft migration at 12 months as compared to 1-month imaging

· Aneurysm expansion > 5mm at 12 months based on imaging findings relative to the 1-month visit

Study description

Background summary

An aortic aneurysm is defined as a dilatation of the aortic vessel greater than 50% of its normal diameter for a given segment of the adhering normal vessel. A thoracic aortic aneurysm (TAA) is a life-threatening condition. Annually, the incidence of TAA in a population-based study is 10.4 per 100,000 person-years, and the Descending Thoracic Aorta (DTA) is involved in about 40% of those cases. The number of people diagnosed with an aneurysm of the DTA is thought to be increasing. Factors that contribute to this rise include increased longevity of the population and improved diagnostic capability.

Standard surgical treatment involves a thoracotomy, aortic clamping to re-section the aneurysmal segment and replacement using a Dacron graft. Endovascular stent graft repair consists of transfemoral or iliac introduction of the device. When the stent graft device is deployed and expanded within the aneurysmal blood vessel, it creates a new aortic lumen for the blood flow, excluding the aneurysm sac from blood flow while maintaining perfusion to the lower body. Studies comparing open surgical repair versus endovascular repair concluded that the latter offers a less invasive, less expensive alternative, a decrease in mortality and morbidity in high-risk patients, associated with shorter hospital stay and quicker return to normal activities after surgery. Endovascular stent graft treatment is becoming the standard of care in the management of the whole spectrum of thoracic aortic diseases. Mid-term experiences in using thoracic stent grafts in the management of aneurysm of the DTA have been published reporting satisfactory outcomes.

However, despite the wide spread adoption of Thoracic Endovascular Aortic Repair (TEVAR) in modern treatment of TAAs, not all patients are candidates for TEVAR due to anatomical limitations.
Today*s commercially available stent graft systems have markedly improved upon

first-and second-generation systems dating back from the early 1990s and tend to resolve these issues by addressing such limitations. Despite these enhancements, challenges remain in terms of TEVAR applicability. Next-generation systems are faced with the challenge of minimizing complications and secondary-procedure rates while safely treating increasingly complex and challenging anatomies.

Valiant Evo is Medtronic*s next generation stent graft system for treating lesions of the DTA, based on the commercially available Valiant Captivia Stent Graft System. While the Valiant Evo stent graft was designed using the knowledge and technical experience from previous Medtronic stent grafts such as Talent and Valiant, it is closest in design to Valiant and the Valiant platform was leveraged in designing the Valiant Evo device. The Valiant Evo graft material, although different from Valiant, is leveraged from the commercially available Endurant/Endurant II stent graft, which has also demonstrated safety and effectiveness.

Valiant Evo is designed to allow treatment of patients without the need for alternative access methods, expand overall patient applicability, and improve procedural ease of use of the system.

Study objective

The purpose of the Valiant Evo International Clinical Trial is to demonstrate the safety and effectiveness of the Valiant Evo Thoracic Stent Graft System in subjects with a descending thoracic aortic aneurysm (DTAA) who are candidates for endovascular repair. The Valiant Evo International Clinical Trial is a first-in human experience with the objective to provide clinical data for supporting CE marking via case series and descriptive statistics.
Data collected during this trial may also be used in conjunction with data collected during a concurrently enrolling IDE trial to support commercial approval of the Valiant Evo Thoracic Stent Graft System in the United States.

Study design

The Valiant 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 thoracic stent graft anyway, the intervention in this study is the use of the
Valiant Evo thoracic stentgraft, a third generation thoracic stent.

Study burden and risks

Table J-1 of the Clinical Investigation Plan shows a list of potential adverse events that may be associated with use of the Valiant Evo thoracic stent graft system. The occurrence of the listed complications may lead to a repeat endovascular intervention and/or open surgical repair. Since the Valiant Evo thoracic 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 TAA. 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 TEVAR, except for the EQ-50
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

1. Subject is >=18 years old
2. Subject understands and voluntarily has signed and dated the Patient Informed Consent approved by the Sponsor and by the Ethics Committee for this study
3. Subject presents a DTAA which is localized below the ostium of left subclavian artery (LSA) and above the ostium of celiac trunk
4. Subject has a DTAA that is one of the following:
a. A fusiform aneurysm with a maximum diameter that:
· is >= 50 mm and/or:
· is >= 2 times the diameter of the non-aneurysmal thoracic aorta and/or:
· is <50 mm and has grown >= 5 mm within previous 12 months
b. A saccular aneurysm or a penetrating atherosclerotic ulcer
5. Subject*s anatomy must meet all of the following anatomical criteria as demonstrated on contrast-enhanced CT and/or on contrast-enhanced MRI obtained within four (4) months prior to implant procedure:
a. Proximal and distal non-aneurysmal aortic neck diameter measurements must be >= 16 mm and <= 42 mm
b. Proximal non-aneurysmal aortic neck length must be >= 20 mm (for FreeFlo configuration) and >= 25 mm (for Closed Web configuration)
c. Distal non-aneurysmal aortic neck length must be >= 20 mm
Subject has adequate arterial access site or can tolerate a conduit that allows endovascular access to the aneurysmal site with the delivery system of the

Exclusion criteria

1. Subject has a life expectancy of less than 1 year
2. Subject is participating in another investigational drug or device study which would interfere with the endpoints and follow-ups of this study
3. Subject is pregnant
4. Subject requires planned placement of the covered proximal end of the stent graft to occur in zones 0 or 1
5. Subject has a thoracic aneurysm with a contained rupture or localized at the anastomosis of a previous graft (pseudo-/false aneurysm)
6. Subject has a mycotic aneurysm
7. Subject has a dissection (type A or B) or an intramural hematoma or an aortic rupture in addition to the thoracic aneurysm
8. Subject requires emergent aneurysm treatment, e.g., trauma or rupture

9. Subject has received a previous stent or stent graft or previous surgical repair in the ascending and/or descending thoracic aorta, and/or in the aortic arch
10. Subject requires surgical or endovascular treatment of an infra-renal aneurysm at the time of implant
11. Subject has had previous surgical or endovascular treatment of an infra-renal aortic aneurysm
12. Treatment with the Valiant Evo Thoracic Stent Graft would require intentional revascularization of the brachio-cephalic artery, the left common carotid artery or the celiac trunk
13. Subject has had or plans to have a major surgical or interventional procedure within 30 days before or 30 days after the planned implantation of the Valiant Evo Thoracic Stent Graft. This does not include planned procedures that are needed for the safe and effective placement of the stent graft (i.e., carotid/subclavian transposition, carotid/subclavian bypass procedure)
14. Subject has a significant and/or circumferential aortic mural thrombus at either the proximal or distal attachment sites that could compromise fixation and seal of the implanted stent graft
15. Subject has a connective tissue disease (e.g., Marfan*s syndrome, aortic medial degeneration)
16. Subject has a bleeding diathesis or coagulopathy, or refuses blood transfusion.
17. Subject has had a MI within 3 months of the procedure
18. Subject has had a CVA within 3 months of the procedure
19. Subject has a known allergy or intolerance to the device materials
20. Subject has a known allergy to anesthetic drugs
21. Subject has a known hypersensitivity or contraindication to anticoagulants, or contrast media, which is not amenable to pretreatment
22. Subject has active or systemic infection at the time of the index procedure

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):	08-06-2016

Enrollment:	18
Type:	Actual

Medical products/devices used

Generic name:	Valiant Evo Thoracic Stent Graft System
Registration:	No

Ethics review

Approved WMO Date:	05-04-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-12-2017
Application type:	Amendment
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
CCMO	NL55729.100.15
Other	nog onbekend

Study results

Results posted:	26-02-2024
Actual enrolment:	4

First publication
01-01-1900