Evaluation of the Vascutek Ltd. Thoracic Endovascular Stent Graft System (Thoraflex) in the Treatment of Aneurysm or Penetrating Ulcer of the Descending Thoracic Aorta

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The purpose of this study is to investigate the clinical performance of Thoraflex in the treatment of subjects with aneurysm or penetrating ulcer of the descending thoracic aorta.The primary objective of this study is to demonstrate the safety and...

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

Summary

ID

NL-OMON36276

Source
ToetsingOnline

Brief title
Vascutek Thoraflex Study

Condition

- Aneurysms and artery dissections

Synonym
Thoracic aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Vascutek Limited
Source(s) of monetary or material Support: Funded by study sponsor (Vascutek Ltd)

Intervention

Keyword: Aneurysm, Endovascular, Thoracic, Thoraflex

Outcome measures

Primary outcome

The primary safety endpoint will be the proportion of subjects who do not sustain any major adverse events (MAEs) *30 days post-procedure. A MAE is defined as the occurrence of any of the following:

* Respiratory complications: atelectasis/pneumonia, pulmonary embolism, pulmonary oedema, respiratory failure.

* Renal complications: renal failure, renal insufficiency.

* Cardiac complications: MI, unstable angina, new arrhythmia, exacerbation of congestive heart failure.

* Neurological: New CVA/embolic events, paraplegia/paraparesis

* Aneurysm rupture

* Gastrointestinal: bowel ischemia

* Major bleeding complications (procedural or post procedural), coagulopathy

* Vascular complications

* Death due to device or procedure related complications, internal bleeding, vascular repair, transfusion reaction or conversion to open surgical TAA repair.

The primary effectiveness endpoint will be successful aneurysm treatment, defined as a composite endpoint of subjects who have successful delivery and deployment of the ThoraflexTM at the initial procedure and are free from the following at * 365 days post-procedure:

* Aneurysm growth >5 mm from baseline measurement (Pre-Discharge CT Scan)
* Post-operative interventions to correct type I or III endoleaks
* Conversion to open surgical repair
* Failed patency of the stent graft
* Migration requiring secondary intervention
* Significant failure of stent graft integrity
* Aneurysm rupture

Secondary outcome

Technical Success

Technical success is defined as the introduction and deployment of ThoraflexTM (with any ancillary endovascular components deemed necessary such as extensions or stents) in the absence of mortality, conversion to surgical repair, failed patency or evidence of a type I or III endoleak in the first 24 hour post-operative period (defined on procedural angiography). Components of technical success to be evaluated as secondary effectiveness outcomes include:

* Incidence of type I or III endoleak. The incidence of subjects with freedom from type I and III endoleaks will be the focus of assessments, however type II and IV endoleaks will be recorded and evaluated for rates of occurrence.
* Stent graft patency, defined as the presence of blood flow within the graft as determined through imaging analysis.

* Conversion to surgical repair.

These outcomes will also be evaluated throughout the study, however, only events occurring *24 hours post-procedure will be assessed for technical success. For example, a type I endoleak discovered at 180 days post-procedure will not be considered a technical failure, but will be evaluated as a component measurement. Mortality will be assessed separately as a safety outcome.

Changes in Aneurysm Size

Aneurysm size will be evaluated pre-procedure and at discharge, 1, 6 and 12 months post-procedure. It is anticipated that in the initial post-implant period the aneurysm sac may increase slightly in diameter as has been reported elsewhere for this type of procedure. Therefore, although aneurysm size will be evaluated at 1 month, this will only be evaluated as a component measurement.

A significant size change, compared with pre-procedure, will be considered to be a decrease or increase in diameter >5 mm as measured along the major axis diameter.

Assessment of Aneurysm Rupture

Aneurysm rupture will be defined as the expansion of the blood vessel to the extent of leakage of blood into the body cavity as determined from imaging.

Assessment of Stent Graft Migration and Integrity

Stent graft migration will be defined as proximal or distal migration of the stent graft in excess of 10mm which requires a secondary intervention. Migration will be evaluated at discharge, 1, 6 and 12 months post-procedure. Structural Integrity will be assessed primarily by CT scan images and a 3D reconstruction and will be represented in binomial fashion. The stent graft will be assessed and described in terms of the integrity of the ring stents, the fixation hooks, the struts and the fabric graft material. Categories of stent graft integrity will include intact, fractured, or any failure of the device components to demonstrate structural integrity.

Assessment of Secondary Interventions

The incidence of secondary intervention following device implantation will be evaluated at discharge, 1, 6 and 12 months post-procedure. Secondary interventions may include embolisation of endoleaks, treatment of branch vessel occlusions, placement of new components as a result of migration and open conversions.

Acute Procedural Outcomes

Additional clinical endpoints to assess acute procedural outcomes include duration of procedure and procedural blood loss (volume).

Study description

Background summary

The Thoraflex Thoracic Stent Graft System is designed for the treatment of aneurysm or penetrating ulcer of the descending thoracic aorta. Endovascular repair of aneurysm or penetrating ulcer of the descending thoracic aortic has been demonstrated to be a safe and feasible treatment. In addition endovascular repair may provide a treatment choice to those higher risk patients who are unsuitable for traditional surgery as it offers a less invasive treatment option and is well recognised as showing early advantages and reduced early complications. Despite the recognised benefits, further research and evidence is needed to determine longer-term outcomes of endovascular thoracic aortic repair. Potential limitations of current commercially available systems include the inability to deal with complex aortic anatomies, the inability to navigate iliac tortuosity and stenosis, inadequate sealing and fixation and device fracture / fatigue.

In an attempt to overcome these limitations and prove that the long-term outcomes of endovascular repair of the thoracic aorta are favourable, and as new treatment systems require robust evaluation before they can be adopted into clinical practice, a prospective, non-randomised single-arm study has been designed to evaluate the safety and efficacy of the Thoraflex Thoracic Endovascular Stent Graft System.

Study objective

The purpose of this study is to investigate the clinical performance of Thoraflex in the treatment of subjects with aneurysm or penetrating ulcer of the descending thoracic aorta.

The primary objective of this study is to demonstrate the safety and effectiveness of Thoraflex in the treatment of subjects with aneurysm or penetrating ulcer of the descending thoracic aorta.

The secondary objective of this study is to assess the clinical outcomes of Thoraflex associated with the treatment of aneurysm or penetrating ulcer of the descending thoracic aorta.

Study design

This is a prospective, non-randomised single-arm study to evaluate the safety and efficacy of the Thoraflex Thoracic Endovascular Stent Graft System in the treatment of aneurysm and penetrating ulcer of the descending thoracic aorta. 143 subjects will be recruited from up to 30 centres in Italy, France, Germany,

Netherlands, Belgium, Canada and the UK. All Investigators will be experienced in the endovascular treatment of patients with thoracic aneurysm or penetrating ulcer.

Subjects will be evaluated pre-operatively, intra-operatively, at discharge, 30 days, 6, 12, months post-operatively. Each post-operative evaluation will consist of CT scan and physical examination. This evaluation schedule represents standard best clinical practice for patients undergoing thoracic stent graft treatment with an approved device. Therefore, follow up within the study should confer no additional burden on the study subjects. Adverse event data will be collected throughout the study.
Success criteria will be:

Safety (freedom from Major Adverse Events)

and

Efficacy (successful aneurysm or ulcer treatment)

Intervention

Endovascular implant of a stent graft. Each stent graft is advanced from a transfemoral or transiliac approach over a 0.035* guidewire and positioned under fluoroscopic control. If necessary, an arterial conduit technique may be required to allow access to the arterial system. The soft tapered tip allows atraumatic insertion into the vessel, while the catheter and sheath are designed to provide excellent flexibility and control through tortuous arterial anatomy.

Each individual stent graft device is supplied sterile and pre-loaded in a single-use delivery system. The stent graft is a self-expanding endoprosthesis constructed of a thin wall woven polyester and Nitinol ring stents, which are attached to the fabric with braided polyester sutures. The delivery system central catheter is a stainless steel braided co-extrusion of PTFE and polyester elastomer, designed to provide significant torque control and strength, while also maintaining superior flexibility. The outer sheath is made in a tri-layer construction consisting of a PTFE liner, a stainless steel flat braid layer and a polyester elastomer outer jacket with a hydrophilic lubricant coating. These materials provide very low friction force during device insertion and deployment together with enhanced flexibility of the delivery system. The handle components are moulded from thermoplastic polyurethane.

The materials of the endoprosthesis are identical to those of the current CE marked Vascutek Ltd. Anaconda Stent Graft System intended for abdominal aortic aneurysm repair. The materials of the delivery system are well established in medical applications. The design and apllication of Thoraflex is based on the

same principles as other clinically established thoracic endovascular devices. The endoprosthesis is constructed of self-expanding nitinol stents covered by a fabric tube graft. Four proximal hooks anchor the endoprosthesis within the aorta. Unlike existing thoracic endovascular devices, the delivery system of the Thoracic Endovascular Stent Graft System allows repositioning of the endoprosthesis so that the optimal deployment position can be enhanced.

Study burden and risks

Study subjects will be patients requiring endovascular repair of an aneurysm or ulcer of the descending thoracic aorta. Preoperative, intraoperative and postoperative care of study patients follows current best clinical practice. Therefore, subjects recruited to the study should receive identical care to those treated outside of the study and experience no additional burden from participation in the study.

Risks associated with participation in the study relate specifically to this being the first human in-vivo use of this device. Thoraflex has undergone comprehensive pre-clinical testing, which includes in vitro and in vivo evaluation, which demonstrates safety for the intended use.

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

Patients with aneurysms or penetrating ulcers of the descending thoracic aorta;Main Inclusion criteria:
1.Subject ages > 18 years
2.Subject has a life expectancy of at least 12 months
3.The Subject must meet at least one of the following:
- Descending thoracic fusiform aneurysm, 50mm in diameter or greater.
- Descending thoracic aneurysm that is 4cm or more in diameter that has increased in size by 0.5cm in last 6 months
- Descending thoracic aneurysm with a maximum diameter that exceeds two times the diameter of the non-aneurysmal, adjacent aorta
- Saccular aneurysm in the descending thoracic aorta or Penetrating Atherosclerotic Ulcers (PAUs)
4. The diagnosis is confirmed as thoracic aortic aneurysm or PAU by contrast enhanced CT obtained within the three months prior to implant.
(all 9 inclusion criteria can be found in the protocol section 5.1)

Exclusion criteria

Main exclusion cirteria:
1. Subject has any of the following conditions in his/her descending thoracic aorta:
- Dissections - acute or chronic, in ascending or descending aorta
- Acute Transection or Acute Traumatic Injury
- Pseudoaneurysm (false aneurysm)
- Symptomatic Aneurysm, including ruptured lesions
2. Subject's proximal neck diameter, < 22 or > 35 mm.
3. Subject's distal neck diameter, < 22 or > 35 mm.
4. Subject has prohabitive calcification(>50% circumferential calcification), occulsive disease or tortuosity of intended fixation sites.
(All 25 exclusion criteria can be found in the protocol section 5.2)

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):	17-11-2011
Enrollment:	22
Type:	Actual

Medical products/devices used

Generic name:	Vascutek Ltd. Thoracic Endovascular Stent Graft System (Thoraflex)
Registration:	No

Ethics review

Approved WMO

Date:	12-05-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	27-10-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	28-10-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	21-11-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL31772.068.10
Other	not available yet