Prospective, Multicenter, Single Arm Feasibility and Safety Study of the Endologix Fenestrated Stent Graft System for the Endovascular Repair of Juxtarenal/Pararenal (JAA/PAA) Aneurysms

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

Summary

ID

NL-OMON37423

Source
ToetsingOnline

Brief title
Ventana Study

Condition

- Aneurysms and artery dissections

Synonym
a bulge in a part of the aorta, cardiovascular disease

Research involving

Human

Sponsors and support

Primary sponsor: Endologix Inc.
Source(s) of monetary or material Support: Endologix Inc.

Intervention

Keyword: endovascular, feasability, fenestrated stent graft system, juxtarenal/pararenal aneurysms

Outcome measures

Primary outcome

Safety: Major adverse events at 1 month.

Feasibility: Successful device delivery and deployment with patency of the

renal and aortic endografts without Type I/III endoleak at 1 month.

Procedural, clinical, and assisted clinical feasibility will be reported.

Secondary outcome

Additional evaluations include:

* Procedural and in-hospital evaluations: Anesthesia time; fluoroscopy time;

contrast volume used; total procedure time; estimated blood loss; % of patients

with transfusion; time in ICU; time to hospital discharge.

* Death (all-cause and aneurysm-related) within 30 days, at 6 months, and

annually at 1 to 5 years;

* Major adverse events after 30 days, at 6 months, and annually at 1 to 5 years;

* Individual major adverse event components within 30 days, at 6 months, and

annually at 1 to 5 years;

* Aneurysm rupture within 30 days, at 6 months, and annually at 1 to 5 years;

* Conversion to open repair within 30 days, at 6 months, and annually at 1 to 5

years;

* Adverse Events: All serious and non-serious events within 30 days, at 6 months, and annually at 1 to 5 years;

* Distal blood flow (ankle-brachial index evaluations) pre-discharge and at 30 days, 6 months, and annually at 1 to 5 years;

* Endograft performance (aneurysm sac diameter changes; device migration; incidence of endoleak) at 30 days, 6 months, and annually at 1 to 5 years;

* Renal function as assessed by estimated glomerular filtration rate (eGFR) pre-discharge and at 30 days, 6 months, and annually at 1 to 5 years;

* Renal stent graft patency and integrity at 30 days, 6 months, and annually at 1 to 5 years;

* Stent graft (fenestrated/bifurcated) patency and integrity at 30 days, 6 months, and annually at 1 to 5 years;

* Secondary procedures within 30 days, at six months, and at years 1through 5 for resolution of endoleak, limb occlusion, migration, aneurysm sac expansion and/or a device defect.

Study description

Background summary

An extensive summary of current scientific literature regarding surgical and endovascular techniques and devices used in the repair of JAA or PAA is provided in the Clinical Investigator*s Brochure (CIB). A brief summary is provided below: An arterial aneurysm is a permanent, localized dilatation of an artery with an increase in diameter of 50% or more than the normal artery diameter. Although any artery may develop an aneurysm, most commonly an aneurysm is seen in the abdominal aorta, thoracic aorta, popliteal artery or common iliac artery. Abdominal aortic aneurysm (AAA) is a progressive disease

characterized by structural deterioration, gradual expansion, and eventual rupture of the abdominal aorta if left untreated. AAA is the most common type of aortic aneurysm, with more than 90% occurring inferior to the renal arteries. This vascular disorder causes significant mortality and morbidity in the aged population and is a leading cause of death. The complexity of AAA is commonly characterized based on location and involvement with visceral vessels. Infrarenal AAA generally involves the infrarenal aorta and may involve the aortoiliac vasculature. A subset of infrarenal AAA extends up to the level of but does not involve the renal arteries, and is termed juxtarenal AAA (JAA). A small proportion of AAA involves the renal arteries and as such is termed pararenal AAA (PAA). Extension of the disease to and beyond the superior mesenteric artery (SMA) or celiac artery (CA) into the thoracic aorta describes thoracoabdominal aneurysms. These more complex aneurysms are beyond the scope of this study. It is estimated that approximately 25% to 40% of infrarenal AAA are not suitable for endovascular repair due to unfavorable proximal neck anatomy (e.g., highly angulated, dilated, short [JAA], or encroaching on or involving the renal arteries [JAA or PAA]).In most US studies of endovascular AAA repair, including that for the Endologix Powerlink System, the infrarenal non-aneurysmal neck length and angulation to the aneurysm sac requirements are *15mm and *60°, respectively; shorter lengths or greater angulation have been reported to increase the risk of migration and Type 1A endoleak and associated need for intervention.Owing to the increased risk of renal complications, mesenteric ischemia and other complications following open repair of JAA or PAA compared to infrarenal AAA or hybrid open visceral debranching techniques, researchers have sought to extend a totally endovascular technique to repair of these aneurysms. To consider application of an endovascular method to JAA or PAA repair, it is essential to maintain the patency of visceral vessels (i.e., renal arteries; SMA; CA). Browne and colleagues reported their feasibility experience in the construction and implant of home made fenestrated stent grafts using Dacron graft and stainless steel Z-stents in the canine model. Each fenestration was sized to approximate the size of the arterial ostium, an improvement over prior reports suggesting that oversizing of the fenestration may be necessary to ensure the ostia are not covered. Six hours after implant, animals were sacrificed and the positioning of all fenestrations verified. No ostial obstruction was observed, and the devices were widely patent. Several single center clinical case reports have described the use of *homemade* fenestrated stent grafts fashioned by physicians from commercially available stent grafts for the endovascular repair of JAA/PAA. Although cited as technically feasible in some patients, the broad application of this approach does not appear to be generally accepted by the medical community. A number of single center and several multicenter reports of a custom device based on the Cook Zenith stent graft are available in the literature. The key limitation to this approach is the need to customize the design and manufacture of each stent graft to a particular patient anatomy. This requires a lengthy period of time for planning, manufacture, and delivery of the device. More recently, several publications attempt to propose methods for modifying this customization algorithm broaden the applicability of a

particular device to more than one patient. That is, to create an *off-theshelf* fenestrated stent graft device. Endologix, Inc. has developed a Stent Graft System based on the approved Powerlink design that is specifically intended as a potential *off-the-shelf* endovascular repair option for JAA/PAA. This design couples the CE Marked and U.S. FDA-approved Powerlink bifurcated stent graft with a fenestrated/scalloped proximal extension and renal stent grafts with the intent to be applicable to approximately 80-90% of patients presenting with JAA/PAA.

Study objective

The primary objective of this study is to assess the feasibility and safety of the Endologix Fenestrated Stent Graft System for the endovascular repair of juxtarenal or pararenal (JAA/PAA) aortic aneurysms in suitable patients. The primary purpose of this study is to support CE Mark approval for the Endologix fenestrated proximal extension and renal stent graft devices.

Study design

This is multicenter, prospective, single arm clinical feasibility/safety study.

Intervention

Endologix Fenestrated JAA/PAA proximal extension stent graft devices
Endologix renal stent graft devices

Study burden and risks

The decision to repair an aortic aneurysm is generally based on the risk of rupture, the risk of complications of surgery, and patient preference. There are currently two methods used to repair aortic aneurysms. The most common and conventional method is an open surgical repair, with the implantation of a synthetic graft to replace the diseased aneurysmal vessel through a large abdominal incision. Recent technological developments have resulted in an alternative, minimally invasive, endovascular aneurysm repair, in which a stent graft is placed within the aorta through a small incision in the groin. Blood can then flow through the stent graft and is excluded from the aneurysmal portion of the aorta.
The disadvantages of open surgical repair are: general anesthesia is required, it is a major abdominal surgery (large incision), has a significant surgical complication rate, and typically requires a long hospital stay and recovery. EVAR enables local or regional anesthesia to be used, uses a minimally invasive groin incision for catheter-based access, and has been reported in US clinical studys to offer a lower operative
complication rate, reduced blood loss and procedure times, and shorter hospital stay. In contrast to open repair, EVAR is a relatively new treatment, long term

results have not been fully established, and life long surveillance is recommended to verify stent graft integrity and patency and continued aneurysm exclusion. Currently, five device systems are FDA-approved and marketed in the US for endovascular abdominal aortic aneurysm repair. All of these devices require the introduction of catheter-based treatment devices varying in outer diameter profile from 20Fr to 25Fr (ipsilateral). Standard vascular exposure is indicated for access. Prospective clinical study results support the safety and effectiveness of
these stent grafts through early follow-up (to 30 days) and in late follow-up to one year and to up to five years. These and other devices are CE Marked and are available in other international regions. One custom device is CE Marked for JAA endovascular repair; however, no *off-the-shelf* endovascular devices are currently commercially available.
As with any procedure there are risks of serious complications, such as death. The inclusion and exclusion criteria for this population have been carefully established to limit the risk of mortality and morbidity in this population.
The overall risk will be evaluated on an individual basis and discussed with each patient. All of the potential adverse events outlined previously could cause prolonged illness, permanent impairment of daily function or, in rare cases, death. Possible treatments could include, but are not limited to, emergency cardiac or vascular surgery.
Eligibility criteria that exclude patients who are at higher risk for experiencing an anticipated adverse event have been selected to reduce the potential risks to patients who participate in this study. In addition, the assessment of patient anatomy for enrollment by an experienced Core Laboratory is also intended to reduce the potential risks to patients who participate in this study.
Pre-procedural high resolution, contrast-enhanced CT scanning and intraprocedural arteriography will be used to identify and target the aortic anatomy to facilitate the proper introduction, delivery, and deployment of the endovascular repair devices. Physician experience, rigorous application of a common protocol, and careful performance of the procedure with close monitoring of the patient after the procedure will also help to minimize risks.
Alternatives to endovascular repair of JAA/PAA include open surgical repair.

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

Male or female at least 18 years old; informed consent understood and signed and patient agrees to all follow-up visits; have aortic aneurysm with maximum diameter *5.5cm, or between 4.5 and 5.5cm and rapidly expanding (>0.5cm in six months), or >50% larger than normal aortic diameter. Anatomically eligible for the Endologix Bifurcated System per the FDAapproved indications for use (IFU) and for the Fenestrated Stent Graft System.

Exclusion criteria

Life expectancy <2 years as judged by the investigator; Psychiatric or other condition that may interfere with the study; Participating in the enrollment or 30-day follow-up phase of another clinical study; Known allergy to any device component; Coagulopathy or uncontrolled bleeding disorder; Contraindication to contrast media or anticoagulants; Ruptured, leaking, or mycotic aneurysm; Aortic dissection Serum creatinine (S-Cr) level >2.0 mg/dL;Traumatic vascular injury; Active systemic or localized groin infection; Connective tissue disease (e.g., Marfan*s Syndrome);
Recent (within prior three months) cerebrovascular accident or myocardial infarction; Prior renal transplant; Length of either renal artery to be stented <12mm; Significant occlusive disease of either renal artery (>70%); An essential accessory renal artery; Indispensable inferior mesenteric artery; Untreated aneurysmal disease of the descending thoracic aorta; Prior iliac artery stent implanted that may interfere with delivery system introduction; Unsuitable vascular anatomy; Pregnancy (female patient of childbearing potential only).

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-07-2012
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Fenestrated Stent Graft System for the Endovascular Repair of Juxtarenal/Pararenal (JAA/PAA) Aneurys
Registration:	No

Ethics review

Approved WMO Date:	08-06-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-07-2012
Application type:	Amendment
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
CCMO	NL39259.091.11

Study results

Date completed:	21-03-2018
Actual enrolment:	5