Prospective, Multicenter, Single Arm Safety and Effectiveness Study of Endovascular Abdominal Aortic Aneurysm Repair using the Nellix® System EVAS I Study

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The objective of this study is to assess the safety and effectiveness of the Endologix Nellix® EndoVascular Aneurysm Sealing System for the endovascular repair of infrarenal abdominal aortic aneurysms (AAA). Procedures will be performed per the...

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

Summary

ID

NL-OMON38484

Source
ToetsingOnline

Brief title
EVAS-I Study

Condition

- Aneurysms and artery dissections

Synonym
dilatation of the abdominal aorta, Enlarged artery of the abdominal aorta

Research involving
Human

Sponsors and support

Primary sponsor: Endologix, Inc
Source(s) of monetary or material Support: Endologix Inc geeft een vergoeding voor datamanagement tijdens de EVAS-I studie. De extra CT scans (2x) gedurende follow-up worden vergoed. Verder zijn er geen additionele kosten voor het ziekenhuis aan verbonden.

Intervention

Keyword: Abdominal aortic aneurysm, Endoprothesis, Endovascular aortic repair

Outcome measures

Primary outcome

6.1. PRIMARY SAFETY

The safety endpoint is defined as the incidence of Major Adverse Events (MAE)

at 30 days, defined as the composite of the following. Event definitions are

provided in §8.7.7.

* All-Cause Mortality;

* Bowel Ischemia;

* Myocardial Infarction;

* Paraplegia;

* Renal Failure;

* Respiratory Failure;

* Stroke;

* Procedural Blood Loss *1,000mL

6.2. PRIMARY EFFECTIVENESS

The primary effectiveness endpoint is defined as the rate of Treatment Success

at one year. Treatment Success is a composite of outcomes clinically relevant

to the endovascular repair of infrarenal AAA as follows. Event and related

definitions are provided in §8.7.7.

Treatment Success: Procedural technical success and absence of:

* Abdominal aortic aneurysm rupture;

* Conversion to open surgical repair;

* Endoleak Type I or III at 12 months;

* Clinically significant migration;

* Aneurysm enlargement; or

* Secondary endovascular procedure up to 12 months for resolution of

* Endoleak (Type I or Type III)

* Device obstruction or occlusion

* Device migration

* Abdominal aneurysm sac expansion

* Device defect.

Refer to §10.7 for primary effectiveness endpoint analysis details.

Secondary outcome

Additional evaluations include:

* Procedural and In-Hospital Evaluations:

o Volume of contrast media used; o Estimated

blood loss;

o Fluoroscopy time; o %

requiring blood transfusion;

o Total procedure time;

o Anesthesia time;

o Time in ICU; o Time

to hospital discharge;

* Mortality, all-cause and aneurysm-related, within 30 days, at 6 months, and

annually to 5 years;

* MAE Individual Components within 30 days, at 6 months, and annually to 5

years;

* Composite MAEs after 30 days, at 6 months, and annually to 5 years;

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

* Conversion to Open Surgical Repair within 30 days, at 6 months, and annually

to 5 years;

* Adverse Events (serious and non-serious) within 30 days, at 6 months, and

annually to 5 years;

* Device Performance (aneurysm sac diameter change from the first

post-operative visit; device migration; clinically significant device

migration, incidence of endoleak) at 30 days, 6 months, and annually to 5 years;

* Renal Function pre-discharge and at 30 days, 6 months, and annually to 5

years, as assessed by the estimated glomerular filtration rate (eGFR) and

changes over time;

* Device Patency and Integrity within 30 days, at 6 months, and annually to 5

years, as determined by contrast-enhanced CT scan, and as assessed by the

independent core laboratory, inclusive of:

o Patent luminal

flow o Absence of

kinking or occlusion

o Absence of stent

fracture o Absence of device failure

* Luminal Thrombus Requiring Intervention within 30 days, at 6 months, and

annually to 5 years;

* Secondary Procedure within 30 days, at 6 months, and annually to 5 years for

resolution of endoleak, device occlusion, migration, aneurysm sac expansion

and/or a device defect.

Study description

Background summary

Mortality due to AAA rupture ranks 13th in the United States and 10th in Canada among men older than 65 years. In addition, several authors have suggested an increase in the mortality rate due to rupture of AAA in the past decades in both the United Stated and England, with more than 14,000 and 7,259 deaths/year in those respective countries. Despite being significant, such figures are probably underestimated, because many deaths resulting from ruptured aneurysms are not verified by autopsy, and are consequently not documented. Some researchers have reported that the overall lethality associated with rupture of AAA approaches 80%, including dead-on-arrival-subjects or those who die before the diagnosis is made.
AAA is defined clinically as a focal dilatation of the aorta causing a diameter increase of >50% of the expected normal diameter. Although any artery may develop an aneurysm, they are most commonly observed in the infrarenal abdominal aorta, thoracic aorta, popliteal artery and common iliac artery.
The principal risks related to aneurysms are rupture and thrombus migration. Aneurysms slowly and continually increase in size leading to the aneurysm rupture. The larger an aneurysm becomes, the likelihood of eventual rupture increases. The natural history of aortic aneurysms is to enlarge and rupture. Other potential complications of the aneurysm include compression of adjacent organs which may result in aortoenteric fistula, or aortocaval fistula. If the thrombus embolizes and flows down the blood stream, this can induce acute or chronic arterial obliteration of the lower limbs.
The risk of rupture is weighed against the risk of perioperative morbidity. The United Kingdom Small Aneurysm trial (UKSAT) reported 103 aneurysm ruptures in

2,257 subjects over a period of seven years, with an annual rupture rate of 2.2%. The decision to treat a patient that presents with an asymptomatic aneurysm primarily dependents upon the size of the aneurysm. Current Society for Vascular Surgery (SVS) practice guidelines recommend surveillance for most subjects with a fusiform AAA in the range of 4.0 to 5.4cm in maximum diameter; therefore, surgical repair of abdominal aneurysms of 5.5 cm or greater in diameter is recommended in healthy subjects, as is repair of saccular aneurysms.

It is estimated that approximately 25% to 40% of infrarenal AAA are not suitable for endovascular aneurysm repair (EVAR) due to unfavorable proximal neck anatomy (e.g., highly angulated, dilated, short, or encroaching on or involving the renal arteries. In most studies of endovascular AAA repair, 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.

When selecting the specific stent graft to be used for EVAR, the characteristics of the graft must be considered in light of the patient*s anatomic and physiologic characteristics. Endovascular devices vary in the type of stent design. For example, most of the currently available devices seal aneurysms by proximal and distal fixation of the stent graft by either active fixation (anchoring pins) or oversizing the stent diameter for increased radial force thereby achieving seal and excluding the aneurysm sac lumen. Greater than 25% of subjects develop an endoleak (mostly type II endoleaks due to back-bleeding of lumbar or visceral arteries within the aneurysm sac) within the first two years following endoluminal stent-graft repair, and approximately 15-20% of the endoleaks persist at five years.8 Endoleaks may lead to sac enlargement and migration and may require reintervention, using either catheter-based techniques or conversion to open repair. These secondary procedures increase the risk to the patient and increase the cost of treatment. Accordingly, EVAR subjects are routinely monitored annually by contrast-enhanced CT scan after treatment contributing further to treatment costs and increasing patient exposure to nephrotoxic contrast agents and radiation. Recent reports suggest contrast nephrotoxicity affects 7 to 12% of subjects after CT angiography.

The Nellix System was designed to withstand the migration and lateral displacement forces acting on endografts, while at the same time excluding the aneurysm sac lumen and minimizing endoleaks of any kind. The system is comprised of two independent flow channels, one to each iliac artery. Each flow channel consists of a balloon-expanded ePTFE covered stent surrounded by a Polymer-filled EndoBag which fills the blood lumen within the aorta, thus providing positional stability of the endograft and sealing the aneurysm completely from side-branch flow. A clinical trial has been performed to assess the safety and effectiveness of the first generation Nellix system for endovascular AAA repair and results serve as the basis for CE Mark approval (October 2012); initial results to one year have been reported. Results of this trial demonstrate the versatility of the Nellix System in treating a

variety of AAA anatomies, including those that have common iliac artery involvement bilaterally.
Continued clinical evaluation of the Nellix System in a broader group of institutions and physicians is therefore appropriate to assess the safety and effectiveness of the device for AAA repair and the generalizability of the approach.

Study objective

The objective of this study is to assess the safety and effectiveness of the Endologix Nellix® EndoVascular Aneurysm Sealing System for the endovascular repair of infrarenal abdominal aortic aneurysms (AAA). Procedures will be performed per the Nellix Instructions For Use (IFU) and per institutional protocols and standard of care for endovascular aneurysm repair. As such, this study will evaluate the safety and effectiveness of this device system among a wide range of physicians and in consecutively enrolled subjects to assess outcomes generalizability.

Study design

This is a multicenter, prospective, single arm clinical study. Subjects with infrarenal AAA who are suitable candidates for endovascular repair using the Nellix System, based on protocol Inclusion/Exclusion criteria, will be considered for enrollment.
After this protocol and the patient informed consent form are reviewed and approved by the local Ethics Committee/Institutional Review Board (EC/IRB), patients having infrarenal AAA will be offered participation in the study. This will be accomplished through the patient*s reading of the informed consent form in the patient*s native language and discussion of the study with the patient by the Principal Investigator (PI) and site personnel. Agreement to participate and to attend all follow-up visits will be documented with the patient*s signature on the informed consent form, with appropriate signatures.
After providing written informed consent, screening and eligibility determinations will be performed by the site, Core Lab, Independent Anatomical Evaluation and Endologix. Subjects will undergo a high resolution, contrast-enhanced computed tomography angiography (CT) scan of the relevant aortic and aortoiliac vasculature within three months of the scheduled procedure(standard of care). Evaluation of the aortic and vascular anatomy suitability per this protocol, as depicted on the CT scan, will be performed by the site PI and by an independent core laboratory and will undergo independent medical evaluation. Other tests include a physical examination, review of medical history for exclusionary conditions, and selected blood laboratory analyses. Endologix will notify, in writing, each potential patients final eligibility status before a case may be scheduled.
Following discharge from the hospital, the first follow-up visit will be made at 30 days (±2 weeks). A CT scan will be performed to assess aneurysm

morphology and device integrity and patency, as well as the status of the implanted devices. Subsequent follow-up visits will be made at six months, one year, and annually to five years per institutional standard of care for subjects with endovascular stent grafts. Continued subject follow-up beyond five years is outside of the scope of this study. Nonetheless, all subjects should be monitored and evaluated per the institutional standards of care for patients with an implanted endovascular stent graft.

Intervention

Patients with an indication for treatment of their infrarenal abdominal aortic aneurysm will be treated with the Nellix system according to the instructions for use.

Study burden and risks

Risks and participation in this study are similar to the usual and current risks associated with endovascular treatment of infrarenal abdominal aortic aneuryms. Follow-up will be according to current standard care, except that two extra CTscans (1 month and 6 months after treatment) will be performed if the condition of the patient will allow this. (In case of renal failure or objection by patient or surgeon these will not be performed)

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;
*Patient agrees to all follow-up visits;
*Have an infrarenal abdominal aortic aneurysm (AAA) with maximum sac diameter *5.5cm, or an infrarenal AAA * 4.5 cm which has increased by >1.0cm in the past year.
*Anatomic eligibility for the Nellix System per the instructions for use:
oAdequate iliac/femoral access compatible with the required delivery systems (diameter 6 mm);
oAneurysm blood lumen diameter *60mm;
oProximal non-aneurysmal aortic neck:
* length 10mm;
* lumen diameter 16 to 32mm;
* angle 60° to the aneurysm sac;
oMost caudal renal artery to each hypogastric artery length 100mm;
oCommon iliac artery lumen diameter between 8 and 35mm;
oAbility to preserve at least one hypogastric artery.

Exclusion criteria

* Life expectancy <2 years;
* Psychiatric or other condition that may interfere with the study;
* Participating in another clinical study
* Known allergy to device any device component;
* Coagulopathy or uncontrolled bleeding disorder;
* Ruptured, leaking or mycotic aneurysm;
* Serum creatinine level >2.0mg/dL;
* CVA or MI within three months of enrollment/treatment;
* Aneurysmal disease of the descending thoracic aorta;
* Clinically significant infrarenal mural thrombus (>5mm thickness over >50% circumference);
* Connective tissue diseases (e.g., Marfan Syndrome)

* Unsuitable vascular anatomy;
* Pregnant (females of childbearing potential only).

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):	17-01-2014
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	The Nellix system (endoprothesis)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-02-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	09-07-2014
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
Other	Clinicaltrial.gov: NCT01726257
CCMO	NL46684.091.13

Study results

Results posted: 13-01-2023

First publication
07-12-2022