EASYII - A Post-Market Clinical Follow-up Study (PMCF) in patients with infrarenal aortic aneurysm undergoing endovascular stenting with the E-tegra Stent Graft System - imaging cohort

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To assess the stent stability and durability as well as the seal of the stent graft during the cardiac cycle and over time as well as to evaluate safety and clinical performance of the Etegra Stent Graft System used in endovascular treatment of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Aneurysms and artery dissections
Study type	Observational invasive

Summary

ID

NL-OMON55918

Source
ToetsingOnline

Brief title
EASYII

Condition

- Aneurysms and artery dissections

Synonym
infrarenal aortic aneurysm, widening of abdominal aorta

Research involving
Human

Sponsors and support

Primary sponsor: JOTEC GmbH
Source(s) of monetary or material Support: Sponsor: JOTEC GmbH

Intervention

Keyword: E-tegra Stent Graft, infrarenal aortic aneurysm

Outcome measures

Primary outcome

Primary Safety Endpoint:

• Rate of 30-day mortality

Primary Imaging Endpoint:

• Quantifying stent stability and durability as well as the seal of the stent graft during the cardiac cycle and over time at 30 day follow-up

Secondary outcome

• Stent stability and durability as well as the seal of the stent graft during the cardiac cycle based on ECG-gated CT scans at prior to discharge, 6, 12, and optionally at 24 months follow-up

• Stent stability and durability as well as the seal of the stent graft over time based on ECG-gated CT scans at prior to discharge, 6, 12, and optionally at 24 months follow-up

• Rate of all-cause mortality in perioperative period (24 h)

• Rate of all-cause mortality at 12, 24, 36 and 60 months

• Rate of aneurysm-related mortality at 30 days, 12, 24, 36 and 60 months

• Rate of aneurysm rupture-related mortality at 30 days, 12, 24, 36 and 60

months

• Rate of patients with aneurysm rupture at 30 days, 12, 24, 36 and 60 months

• Rate of patients with technical success 24 h after the intervention

• Rate of patients with clinical success at 12 months

• Rate of patients with any reintervention at 30 days, 12, 24, 36 and 60 months

• Rate of patients with reintervention-free survival at 12 months follow-up

• Rate of patients with primary E-tegra Stent Graft limb patency at 30 days,

12, 24, 36 and 60 months

• Rate of patients with secondary E-tegra Stent Graft limb patency at 30 days,

12, 24, 36 and 60 months

• Rate of patients with stable aneurysm size on CTA scan at 12 and 60 months

• Rate of patients with decreasing aneurysm size on CTA scan (<= 5 mm in maximum

diameter) at 12 and 60 months

• Rate of patients with aneurysm growth on CTA scan (>= 5 mm in maximum

diameter) at 12 and 60 months

• Rate of patients with stable AAA volume on CTA scan at 12 and 60 months

• Rate of patients with decreasing AAA volume on CTA scan (<= 5 %) at 12 and 60

months

• Rate of patients with increasing AAA volume on CTA scan (>= 5 %) at 12 and 60

months

• Rate of patients with major adverse events at 30 days, 12, 24, 36, and 60

months

• Rate of patients with Type Ia endoleak at 12 and 60 months

• Rate of patients with Type Ib endoleak at 12 and 60 months

• Rate of patients with Type II endoleak at 12 and 60 months

• Rate of patients with Type III endoleak at 12 and 60 months

• Rate of patients with Type IV endoleak at 12 and 60 months

• Rate of patients with endoleak of unknown origin at 12 and 60 months

• Rate of patients with stent graft migration > 10 mm at 12 and 60 months

• Rate of patients with stent graft dislodgement (full component separation) at

30 days, 12, 24, 36, and 60 months

• Rate of patients with stent fracture at 12 and 60 months

• Rate of patients with stent graft infection at 30 days, 12, 24, 36, and 60

months

• Rate of patients with the same level of health status as prior to surgery at

6, and 12 months

• Rate of patients with the same level of QoL as prior to surgery at 6, and 12

months

Study description

Background summary

An aneurysm is a local dilatation or widening of an artery, most commonly being fusiform in shape. An abdominal aortic aneurysm (AAA) is located in the abdominal aorta, most often inferior of the renal arteries.
Stents are vascular implants that are advanced under radioguidance through the blood vessels to the diseased location in the body where they are placed. The insertion sites are on both sides of the groin. The E-tegra Stent Graft System is a class III product. It is CE-marked for endovascular treatment of patients that fulfil the indications for use.
The sponsor will use the study data for a scientific assessment of the performance of the E-tegra Stent Graft System in the treatment of abdominal aortic aneurysms.
The decision by the medical team to treat the patients with the E-tegra Stent

Graft System will be made independently of the study. All the treatment methods are part of the standard of care for patients and will be performed in the same way whether or not the patient participates in the study, except the ECG-gated CTAs which are the study specific exams.

Study objective

To assess the stent stability and durability as well as the seal of the stent graft during the cardiac cycle and over time as well as to evaluate safety and clinical performance of the Etegra Stent Graft System used in endovascular treatment of infrarenal aortic aneurysm.

Study design

Post-Market Clinical Follow-up Study (PMCF):
In this study, patients will be observed who are treated with an aorto-iliac bifurcated or aorto-uni-iliac configuration of the E-tegra Stent Graft System for the treatment of an infrarenal aortic or aorto-iliac aneurysm. The E-tegra Stent Graft components will be implanted at the discretion of the treating physician according to the local protocols.
The EASYII study is conducted to further assess, within the scope of the intended purpose, the E-tegra Stent Graft, including the study specific additional exams (ECG-gated CTAs, additional visit at 6 months).

Study burden and risks

As the EASYII study is a PMCF study, risks or benefits related to the implantation of the Etegra device are not considered as related to the study. Only risks/benefits related to the ECGgated CTA which is the only study specific procedure not part of the hospital's standard of care should be considered as related to the study.

Risks:
Patients will be exposed to a higher radiation (approximately 3.5 mSv per 2 years). Theoretically, this might increase the risk of cancer by less than 0.04% (see chapter 6.2.2). The additional use of contrast medium at 6 months follow-up might increase the risk of renal failure.

Risks mitigation:
Patients will be informed that it is not desirable to participate in other research studies involving exposure to radiation at the same time. The routinely performed static CTA scans at visit preoperative planning, prior to discharge or 30 days and 12 months will be replaced by the ECGgated CTA scans. To mitigate the risk of renal failure patients with an eGFR < 45 ml/min/1.73 m2 before the intervention will be excluded from the study according to the exclusion criteria. The physician who informs the patient

about this study will explain the additional risks to the patient prior to obtaining the written informed consent.

Benefits:
The use of the ECG-gated CTA during the participation of the study will allow to have a better follow-up of the stent stability and durability as well as the seal of the stent graft during the cardiac cycle and over time. The dynamic endovascular environment of the stent graft is expected to influence long term outcome after EVAR. Understanding the stent - artery interaction is crucial for further device development and may aid the prediction of failure during patient selection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

Inclusion Criteria:
* Age >= 65

* Patient must have an
o infrarenal aortic aneurysm with diameter >= 50 mm in females and >= 55 mm in males, or
o infrarenal aortic aneurysm with 40-50 mm that has increased in size by >= 1 cm per year

* Patient is elegible for treatment inside the instructions for use of the E-tegra Stent Graft System

* Patient is able and willing to undergo follow-up imaging and examinations prior to discharge from the hospital, at 30 days and 6 months, 12 months, and annually thereafter until 5 years follow-up

* Patient understands and has signed the Informed Consent Form prior to intervention

* Patient has a life expectancy of at least 5 years

Exclusion criteria

Exclusion Criteria:
* Patient with severe calcification or thrombi in the proximal sealing zone
* Patient with infectious aneurysm
* Patient with inflammatory aneurysm
* Patient with pseudoaneurysm
* Patient with symptomatic aneurysm
* Patient with ruptured or traumatic aneurysm
* Patient with suprarenal, juxtarenal, or pararenal aneurysm
* Patient with aortic dissection
* Patient with a reversed conical neck that is defined as a > 3 mm distal increase over a 15 mm length
* Patient in which the E-tegra Stent Graft System is used in combination with proximal or distal extenders of another company.
* Patient who is planned to be treated with an adjunctive aortic bare metal stent or a fenestrated stent graft
* Patient who is planned to be treated with a chimney / chimneys in the renal or visceral vessels
* Patient who is planned to be treated with an iliac branch device or parallel grafts in the iliac vessels

* Patient with genetic connective tissue disease (e.g. Marfan syndrome or Ehlers-Danlos syndrome)
* Patient with eGFR < 45 ml/min/1.73 m2 before the intervention
* Patient had or planned to have a major surgical or interventional procedure within 30 days before or 30 days after the planned implantation of the E-tegra Stent Graft System
* Patient with other medical condition that may cause the patient to be non-compliant with the protocol, confound the results, or is associated with a limited life expectancy of less than five years (i.e. heart failure, active malignancy (progressive, stable or partial remission))
* Patient who has been enrolled in another active clinical trial that does not allow inclusion in this trial

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-03-2023
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	E-tegra Stent Graft System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	26-09-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-10-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-04-2024
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	NL80746.091.22