Monocenter Feasibility Study using the fenestrated ANACONDA endograft for juxta- and suprarenal abdominal aorta aneurysm repair

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To test the feasibility of the ANACONDA endograft for the endovascular repair of juxta and suprarenal AAA.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON36025

Source
ToetsingOnline

Brief title
FANA

Condition

- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
aorta aneursym

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: eigen vakgroep

Intervention

Keyword: Anaconda Endograft, feasibility, fenestrated, juxtarenal and suprarenal aorta aneurysma

Outcome measures

Primary outcome

Feasibility of the fenestrated ANACONDA endograft for juxta and suprarenal

aortic aneurysms:

1. Technical success (i.e. exclsuion of the aneurysm; see protocol for more

information)

2. Patency of the endograft and stents

3. Endoleak

4. Migration of the endograft

Secondary outcome

1. Renal and mesenteric function

2. Reintervention

3. cardiopulmonary complications

4. mortality

Study description

Background summary

Abdominal aortic aneurysm is conventionally repaired by open surgery using a prosthetic graft. This method of repair involves laparotomy and cross-clamping of the aorta and has a mortality rate of 5 % (Zarins et al, 1997, EVAR 1, 2005;

EVAR 2 ,2005; DREAM, 2005). In addition the procedure is associated with a complication rate of 15-37% including significant blood loss, infection and a prolonged anaesthetic time. (White et al, 1996). Endovascular aneurysm repair offers potential benefits including reduced operative time, reduced blood loss, decreased post-operative intensive care (Politz et al 2000) and increased 4 years survival compared to open repair (EVAR 1). This is especially the case in relatively healthy patients (EVAR 1, 2005 and EVAR 2, 2005). All these studies only studies endovascular repair in infrarenal AAA.

Since the first report of a juxtarenal abdominal aortic aneurysm (AAA) endovascularly treated with a fenestrated stent graft in 1999,1 a number of published series have demonstrated excellent early and mid-term results of the technique (Greenberg 2004, Ziegler 2007, Verhoeven 2010). A recently published systematic review confirms the potential lower perioperative mortality of the technique in comparison with open repair (nordon 2009). Fenestrated stent grafts are now commercially available and provide an alternative to open surgery, especially in patients who are at increased risk for open repair.

Study objective

To test the feasibility of the ANACONDA endograft for the endovascular repair of juxta and suprarenal AAA.

Study design

Prospective feasibility study in approximately 20 patients
Inclusion period of 2-4 years (in order to include at least 20 patients)
Follow-up as current standard for AAA (life long) with analysis at 2 and 4 years of follow-up (not including the interim analysis; see protocol)

Intervention

ANACONDA fenestrated endograft.

The operation will be performed under local, epidural or general anaesthetic in the operating theatre at the discretion of the surgeon based on individual patient status. The patient will be positioned and prepared as for conventional open surgery. All the implants will be performed by a team of vascular surgeons and interventional radiologists with an EVAR experience of at least 100 implants and supervised by vascular surgeons or interventional radiologist (proctor) with a comparable EVAR experience including at least 10 ANACONDA endografts.

The procedure will require surgical exposure of the Femoral Arteries or Common Iliac Arteries and will be performed by surgical cut down and formation of an arteriotomy. During the procedure intravenous Heparin 5,000 IU or 100 IU

heparin/kg bodyweight will be required for anti-coagulation therapy in accordance with standard endovascular procedures.

Digital subtraction angiography device will be used throughout the operation. A final contrast enhanced high pressure Aortogram will be performed to assess success of aneurysm exclusion.

The surgical technique must be carried out in accordance with the Vascutek Limited instructions for use.

Study burden and risks

Burden and risks are as follows: no exclusion of the aneurysm wich may need extra endovascular treatment during the primary intervention or during follow-up. Conversion to open repair if endovascular repair is not possible whcih may lead to the known risks of open repair. The presence of an endograft does not mean per se that the open rapair will be more difficult or hazardous. During stenting of the renal or meseteric arteries, damage may occur to these vessels which may need further treatment, usually endovascular. This may lead to a deterioration in kidney function. The risk for other complications, i.e. cardiac and infections, is lower compared to the open procedure.

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 aged 18 years - 90 Years
* Patient willing and available to comply with follow up requirements
* Patient can comply with instructions and give informed consent
* Life Expectancy > 2 Years
* AAA > 55 mm in diameter
* Suprarenal proximal neck diameter 18 - 31.5mm
* Inadequate infrarenal aortic neck sealing zone
* Distal Iliac fixation site diameter < =17 mm
* Distal Iliac fixation site >= 20 mm in length.
* Access vessels: Appropriate anatomy, at the physicians discretion, for access vessel suitability
* Aortic neck angulation <= 90 degrees.

Exclusion criteria

Ruptured AAA
* Presence of serious concomitant medical disease or infection
* Low operative risk for open repair
* Known allergy to contrast medium, nitinol or polyester
* Connective tissue disease
* ASA Grade IV or V
* Need for surgical reconstruction of other visceral arteries or inability to place stent in visceralartery
* Presence of > 50% continuous calcification of proximal neck
* Presence of > 50% thrombus in proximal neck
* Other unsuitable anatomy

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):	26-05-2011
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	fenestrated ANACONDA endograft
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	26-05-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	ned. trialregister tc 2842
CCMO	NL35540.044.11