Ruptured Aortic Aneurysm Study with the Aanconda bifurcated endograft. A monocenter, prospective, feasibility pilot study. (RASA)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27520

Source
NTR

Brief title
RASA

Health condition

Geruptureerd aneurysma van de abdominale aorta.

Sponsors and support

Primary sponsor: Terumo Vascutek Limited
Newmains Avenue
Renfrewshire PA4 9RR
SCHOTLAND

Intervention

Outcome measures

Primary outcome

1. Operative mortality, defined as death within the first 30 days or after 30 days if occurring the same hospitalization (in-hospital mortality);

2. Three months mortality from all causes;

3. Aneurysm-related death (secondary to AAA rupture or secondary procedures;

4. Effectiveness of exclusion of the AAA;

5. Major morbidity (i.1. serious adverse events);

6. Operation time;

7. Time to reach successful stiff wire cannulation of the contralateral gate.

Secondary outcome

N/A

Study description

Background summary

N/A

Study objective

The prupose if this study is; to accesss the feasibility of treatment of rAAA with a bifurcated endograft with the magnetic wire system to speed up the contralateral gate access.

Study design

N/A

Intervention

Het herstellen van de geruptureerde of symptomatisch aneurysma van de abdominale aorta door het inbrengen van de Anaconda bifurcated endograft.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients aged > 18 years;

2. Patient with a ruptured infrarenal AAA*. Rupture is defined as extravasation of blood (haemorrhage outside the aortic wall), documented by: (1) preoperative CT examination, or preoperative ultrasound, or intraoperatively at laparotomy/implant. In the case that after treatment there is still doubt whether the AAA is ruptured, rupture should be confirmed by postoperative CT scan or, in the patient¡¦s death, by autopsy;

3. Patient willing and available to comply with follow up requirements after successful treatment;

4. The subject or legal guardian has been informed of the nature of the study and agrees to its provisions and had provided written informed consent;

5. Infrarenal proximal neck diameter 18 ¡V 31.5mm;

6. Parallel or conical infrarenal neck shape;

7. Infrarenal proximal neck length >15 mm;

8. Distal Iliac fixation site diameter < 17 mm;

9. Distal Iliac fixation site > 20 mm in length;

10. Access vessels: appropriate anatomy, at the physician¡¦s discretion.

Exclusion criteria

1. XJuxta or suprarenal extension of aneurysm;

2. XKnown allergy to contrast medium, nitinol or polyester;

3. XNeed for surgical reconstruction of other visceral arteries;

4. XInfra renal aortic angulation > 90o;

5. XPresence of >= 50% continuous calcification of proximal neck;

6. XPresence of >= 80% thrombus in proximal neck;

7. XPresence of reversed conical infrarenal neck;

8. XOther unsuitable anatomy;

9. XThe patient chooses to be treated by open surgery;

10. XPatients with cancer, with is likely to cause death within one year;

11. Patients not fulfilling the inclusion criteria.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2006
Enrollment:	5

Type: Actual

Ethics review

Positive opinion
Date: 29-05-2006

Application type: First submission

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
NTR-new	NL633
NTR-old	NTR693
Other	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A