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

Gepubliceerd: 29-05-2006 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27520

Bron
NTR

Verkorte titel
RASA

Aandoening

Geruptureerd aneurysma van de abdominale aorta.

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Medisch Spectrum Twente
Postbus 50000
A. Stam

Enschede 7500 KA
The Netherlands

Wetenschappelijk

Medisch Spectrum Twente
Postbus 50000
A. Stam
Enschede 7500 KA
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland Status:	Werving gestopt
(Verwachte) startdatum:	23-02-2006

Aantal proefpersonen:	5
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-05-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL633
NTR-old	NTR693
Ander register	: N/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A