Stent for treating aneurysms of the aorta at the level of the renal arteries.

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The fenestrated Anaconda endograft is safe for durable exclusion of juxta and suprarenal AAA.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26210

Bron
NTR

Verkorte titel
FANA

Aandoening

Aneurysma aorta abdominal
Aortic abdominal aneurysm
fenestrated endograft
gefenestreerde endograft
juxtarenaal
suprarenaal

Ondersteuning

Primaire sponsor: Medisch Spectrum twente
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Durable exclusion of juxta en suprarenal AAA.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Juxta- and suprarenal abdominal aortic aneurysms (AAA) are traditionally treated by open repair. Fenestrated endovascular repair offers an alternative to open repair and has been associated with a lower mortality rate. The Anaconda endograft is effective and safe in treating infrarenal AAA.

Objective:

To analyse the safety and effectiveness of the fenestrated Anaconda endograft in treating juxta- and suprarenal AAA.

Study design:

Monocenter feasibility study of the fenestrated Anaconda endograft.

Study population:

Patients with juxta- and suprarenal AAA > 55mm.

Intervention:

Treating juxta- and suprarenal AAA with the fenestrated Anaconda endograft.

Main study parameters/endpoints:

Technical succes of excluding the AAA, patency migration and endoleak rates of the endograft, renal function, cardiopulmonary complications, mortality.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The fenestrated Anaconda endograft has not yet been analyzed in treating juxta- and suprarenal AAA. There is a risk that this endograft is not able to effectively exclude these AAA. In such a case, it may be necessary to treat these AAA with open repair. Renal function deterioration has been described using fenestrated endografts. Overall, fenestrated endografts seem to have a lower morbidity and mortality rate compared to the open repair procedure, which is an obvious benefit for these patients.

Doel van het onderzoek

The fenestrated Anaconda endograft is safe for durable exclusion of juxta and suprarenal AAA.

Onderzoeksopzet

1. Interim analysis after each 10 patients;

2. Interim analysis after 1 year, of all patients;

3. Analysis of the results after 2 and 4 years, before publication.

Onderzoeksproduct en/of interventie

Fenestrated Anaconda endograft.

Contactpersonen

Publiek

Medisch Spectrum Twente, Afdeling Chirurgie
Postbus 50.000
R. Meerwaldt
Enschede 7500 KA
The Netherlands

+31 (0)53 4872000

Wetenschappelijk

Medisch Spectrum Twente, Afdeling Chirurgie
Postbus 50.000
R. Meerwaldt
Enschede 7500 KA
The Netherlands
+31 (0)53 4872000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients aged 18 - 85 years;

2. Patient willing and available to comply with follow up requirements;

3. Patient can comply with instructions and give informed consent;

4. Life Expectancy > 2 Years;

5. AAA > 55 mm in diameter;

6. Suprarenal proximal neck diameter 18 – 31.5 mm;

7. Inadequate infrarenal aortic neck sealing zone;

8. Distal Iliac fixation site diameter < =17 mm;

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

10. Access vessels: Appropriate anatomy, at the physicians discretion, for access vessel suitability;

11. Aortic neck angulation <= 90 degrees.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Ruptured AAA;

2. Presence of serious concomitant medical disease or infection;

3. Low operative risk for open repair;

4. Known allergy to contrast medium, nitinol or polyester;

5. Connective tissue disease;

6. ASA Grade IV or V;

7. Need for surgical reconstruction of other visceral arteries or inability to place a stent in the visceral arteries;

8. Presence of > 50% continuous calcification of proximal neck;

9. Presence of > 50% thrombus in proximal neck;

10. Other unsuitable anatomy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

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	NL2704
NTR-old	NTR2842
Ander register	METc MST : H1104
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A