Covered versus uncovered stents in the common iliac artery.

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Use of covered balloon-expandable stents for advanced atherosclerotic lesions of the common iliac artery lead to lower binary restenosis rates when compared to uncovered balloon-expandable stents.

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

Samenvatting

ID

NL-OMON24897

Bron
NTR

Verkorte titel
DISCOVER

Aandoening

PAOD
Peripheral artery occlusive disease
Atherosclerotic disease
Perifeer vaatlijden
Atherosclerose

Ondersteuning

Primaire sponsor: DEALL: Dutch Endovascular ALLiance. A research cooperation of vascular surgeons and interventional radiologists from Maasstad Hospital, Rotterdam and Sint Antonius Hospital, Nieuwegein.
Overige ondersteuning: Atrium Medical Inc., Hudson, NH

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Absence of binary restenosis rate.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Iliac artery atherosclerotic disease may cause intermittent claudication and critical limb ischemia. It can lead to serious complications such as infection, amputation and even death. Revascularization relieves symptoms and prevents these complications. Historically, open surgical repair, in the form of endarterectomy of bypass, was used. Over the last decade, endovascular repair has become the first choice of treatment for iliac arterial occlusive disease. No definitive consensus has emerged about the best endovascular strategy and which type of stent, if any, to use. However, in more advanced disease, literature is most supportive of primary stenting with a balloon-expandable stent in the common iliac artery. Recently, a PTFE-covered balloon-expandable stent (Advanta V12, Atrium Medical Inc., Hudson, NH) has been introduced for the iliac artery. Covering stents with PTFE has been shown to lead to less neo-intimal hyperplasia and this might lower restenosis rates. However, only one RCT of mediocre quality has been published on this stent in the common iliac artery. Our hypothesis is that covered balloon-expandable stents lead to better results when compared to uncovered balloon-expandable stents.

Objective:

Our primary objective is to assess the absence of binary restenosis rate of endovascular treatment of advanced atherosclerotic lesions of the common iliac artery with a balloon expandable PTFE-covered stent (Advanta V12), when compared to balloon-expandable uncovered stents after a 2-year follow-up.

Our secondary objectives are to assess the reocclusion rate, target-lesion revascularization rate, morphological outcome, clinical outcome, hemodynamic outcome, major amputation rate, complication rate and mortality rate of endovascular treatment of advanced atherosclerotic lesions of the common iliac artery with a balloon expandable PTFE-covered stent (Advanta V12), when compared to balloon-expandable uncovered stents after a 2-year follow-up.

Study design:

A prospective, randomized, controlled, triple-blind, multi-center trial.

Study population:

Human volunteers aged over 18 years, with symptomatic advanced atherosclerotic disease of the common iliac artery, defined as stenoses longer than 3 cm and occlusions. A total of 174 patients will be included.

Intervention:

The control group will undergo endovascular dilatation or revascularization of the common iliac artery, followed by placement of one or more uncovered balloon-expandable stents. The study group will undergo the same treatment, however one or more PTFE-covered balloon-expandable stents will be placed. When necessary, the aorta, external iliac artery, common femoral artery, superficial femoral artery and deep femoral artery will be treated, using the standard treatment.

Main study parameters/endpoints:

The primary endpoints is absence of binary restenosis rate. Secondary endpoints are reocclusion rate, target-lesion revascularization rate, clinical success, procedural success, hemodynamic success, major amputation rate, complication rate and mortality rate. Main study parameters are age, gender, relevant co-morbidity, and several patient, disease and procedure related parameters.

Doel van het onderzoek

Use of covered balloon-expandable stents for advanced atherosclerotic lesions of the common iliac artery lead to lower binary restenosis rates when compared to uncovered balloon-expandable stents.

Onderzoeksopzet

1 month, 6 months, 12 months, 24 months.

Primary and secondary outcomes will be assessed using the following

modalities: Pre- and post-intervention Digital Subtraction Angiography with 3D-reconstruction, RAND-36 (Quality of Life Questionnaire), WIQ (Walking Impairmant Questionnaire, questionnaire for intermittent claudication complaints), Ankle-Brachial Index and Duplex Ultrasonography. If re-stenosis or occlusion is suspected, CT-angiography, MR-angiography or Digital Subtraction Angiography will be performed.

Onderzoeksproduct en/of interventie

Intervention group:

Endovascular stenting of the common iliac artery using the Advanta V12 stent (Atrium Medical Inc., Hudson, NH), a PTFE-covered balloon-expandable stent.

Control group:

Endovascular stenting of the common iliac artery using one of several selected uncovered balloon-expandable stents.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age over 18;

2. Symptomatic, atherosclerotic lesion of the common iliac artery, either a hemodynamically significant stenosis with a length of more than 3 cm, or an occlusion;

3. Signed informed consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Stenosis with a length of less than 3 cm;

2. Presence of a metastatic malignancy, or other disease that limits life expectancy to less than two years;

3. Previous endovascular or surgical treatment of the common iliac artery on the affected side;

4. Inability or unwillingness to comply with the follow-up schedule;

5. Mental disability or language barrier that hinders the ability to understand and comply with the informed consent;

6. Pregnancy or breast-feeding;

7. Severe renal failure (e-GFR <30 mL/min/1.73 m2);

8. Known allergy to iodinated contrast agents or to PTFE;

9. Contra-indication for anti-coagulation;

10. Acute limb ischemia;

11. Occlusion of the abdominal aorta;

12. Aneurysm of the abdominal aorta that is not amenable to endograft placement.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2012
Aantal proefpersonen:	174
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-04-2012
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	NL3229
NTR-old	NTR3381
Ander register	METC TWOR / ABR : 2012_06 / NL37828.101.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A