Covered versus uncovered stents in the common iliac artery.

No registrations found.

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

Summary

ID

NL-OMON24897

Source
NTR

Brief title
DISCOVER

Health condition

PAOD
Peripheral artery occlusive disease
Atherosclerotic disease
Perifeer vaatlijden
Atherosclerose

Sponsors and support

Primary sponsor: DEALL: Dutch Endovascular ALLiance. A research cooperation of vascular surgeons and interventional radiologists from Maasstad Hospital, Rotterdam and Sint Antonius Hospital, Nieuwegein.
Source(s) of monetary or material Support: Atrium Medical Inc., Hudson, NH

Intervention

Outcome measures

Primary outcome

Absence of binary restenosis rate.

Secondary outcome

1. Reocclusion rate;

2. Target-lesion revascularization rate;

3. Clinical success;

4. Procedural success;

5. Hemodynamic success;

6. Major amputation rate;

7. Complication rate;

8. Mortality rate.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2012
Enrollment:	174
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

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

Study results

Summary results
N/A