DISCOVER: Dutch Iliac Stent trial: COVERed balloon-expandable versus uncovered balloon-expandable stents. A prospective, randomized, controlled, triple-blind, multi-center trial comparing PTFE-covered balloon-expandable stents versus uncovered balloon-expandable stents in patients with advanced occlusive disease of the common iliac artery in terms of morphologic, clinical, and hemodynamic outcome after a 2-year follow-up.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON41499

Source
ToetsingOnline

Brief title
Covered versus uncovered balloon-expandable iliac stents.

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arteriosclerosis of the leg, Peripheral Arterial Occlusive Disease (PAOD)

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Atrium Medical Inc.,Atrium Medical Inc., Hudson, NH, USA

Intervention

Keyword: Common iliac artery, PAOD, PTFE-covered stent, Uncovered stent

Outcome measures

Primary outcome

Primary study parameters/endpoints: The primary endpoints are absence of binary restenosis rate, reocclusion rate and target-lesion revascularization rate.

Primary study parameters are age, gender, relevant co-morbidity, and several patient, disease and procedure related parameters.

Secondary outcome

Secondary endpoints are clinical success, procedural success, hemodynamic success, major amputation rate, complication rate and 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.

Study objective

Our primary objective is to assess the absence of binary restenosis rate, the reocclusion rate and target-lesion revascularization 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 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

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.

Study burden and risks

Participating patients will need to make five study-related hospital visits. Four Duplex Ultrasonography (DUS) and five ankle-brachial index (ABI) measurements with treadmill test will be performed. When compared to our standard work-up and follow-up, patients need to make two extra hospital visits, and will receive two extra DUS and ABI measurements with treadmill test. When treadmill test or DUS shows possible restenosis, patients will receive additional CT-angiography, MR-angiography and/or Digital Substraction Angiography. This is standard procedure. Furthermore, patients will be asked to fill out two questionnaires five times. We do not expect an increased risk for patients by participating in this study. Patients who participate may benefit by being treated with a stent that may have a lower restenosis rate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age over 18
- Symptomatic, atherosclerotic lesion of the common iliac artery, either a hemodynamically significant stenosis with a length of more than 3 cm, or an occlusion
- Signed informed consent form

Exclusion criteria

- Stenosis with a length of less than 3 cm
- Presence of a metastatic malignancy, or other disease that limits life expectancy to less than two years.
- Previous endovascular or surgical treatment of the common iliac artery on the affected side.
- Inability or unwillingness to comply with the follow-up schedule.
- Mental disability or language barrier that hinders the ability to understand and comply with the informed consent.
- Pregnancy or breast-feeding.
- Severe renal failure (e-GFR <30 mL/min/1.73 m2)
- Known allergy to iodinated contrast agents or to PTFE.
- Contra-indication for anti-coagulation.
- Acute limb ischemia
- Occlusion of the abdominal aorta
- 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:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-05-2012
Enrollment:	174
Type:	Actual

Medical products/devices used

Generic name:	Advanta V12 PTFE-covered balloon-expandable stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-04-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-11-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-05-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-03-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-03-2015
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL37828.101.12