Treatment of edge-stenosis in endografts, inserted for occlusive disease in the femoral superficial artery (SFA), with Drug Eluting Balloons (DEB).

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The aim of this study is to analyze and evaluate the feasibility and efficacy of treatment with a DEB of edge stenosis of covered stents in the SFA.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON39003

Source
ToetsingOnline

Brief title
ETUDE

Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Stenosis and atherosclerosis in the endograft in the SFA

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: De ballonnen gratis geleverd door firma Medtronic;onderzoek verder in vrije tijd.

Intervention

Keyword: Drug eluting Balloon, Edge-stenosis, Endograft, SFA

Outcome measures

Primary outcome

Patency rates after treatment with DEB (after 30-days and after 1 year)

Secondary outcome

Complications

Study description

Background summary

Patency rates of angioplasty and bare metal stenting of occlusive lesions of the superficial femoral artery (SFA) have improved in recent years. Results, however, are limited by the occurrence of in-stent restenosis (ISR), mainly in longer lesions (>10cm). With the introduction of covered stents the incidence of ISR is reduced, since the covering material will shield the stent from tissue in-growth. Re-stenosis will be limited to the edges of the covered stent (edge stenosis), which is often easier to treat compared with a diffuse ISR. Randomized studies have shown a superior patency of covered stents compared with bare metal stenting in long lesions and a comparable patency with prosthetic above-knee bypass. The optimal treatment modality of edge stenosis remains to be elucidated. Currently an extension of the covered stent is frequently used with the disadvantage of high costs and the possible overstenting of collaterals in the popliteal artery in case of a distal edge stenosis.
Recent studies have described the efficacy of Drug-eluting balloons (DEB) for treatment of ISR. These studies have shown a higher primary patency rate than angioplasty and have shown that the use of DEB limits usage of stents. Previous studies have also described better clinical outcome such as an higher Ankle-Brachial index (ABI), increased walking capacity and increased Quality of Life(QOL).
The effect of paclitaxel lays in the inhibitation of neointimal proliferation. When delivered locally, in small concentrations, this antineoplastic drug provides sustained inhibition of vascular smooth muscle cell proliferation and

migration. Studies have also compared the paclitaxel-eluting balloons with conventional uncoated balloon angioplasty, this resulted in significant reduction in restenosis.

The efficacy of edge stenosis of endoluminal graft with DEB still has not been studied to date. Treating endoluminal edge stenosis with DEB could inhibit extension of stentgrafts and therefore sparing collaterals and postpone surgical interventions. Treatment with DEB may result in high cost-effectiveness. The goal of the current study is to analyze and evaluate the effect of DEB on the occurrence edge stenosis in order to provide data for a randomized controlled trial compared with treatment by an extension of the endograft by additional stenting in the near future.

Study objective

The aim of this study is to analyze and evaluate the feasibility and efficacy of treatment with a DEB of edge stenosis of covered stents in the SFA.

Study design

Prospective feasibility study.

Intervention

An angioplasty of the lesion will be performed, according to the local protocols. Afterwards the lesion will be treated with a paclitaxel-eluting balloon .

Study burden and risks

Based on our current knowledge, participating in this study with paclitaxel-eluted balloons has no additional risks. Previously studies have already shown better clinical outcomes compared to conventional angioplasty. Therefore we think that the patients wil profit from this intervention. In every clinical study unexpected and still unknown complications can occur. Obviously every effort possible, will me made to minimize the risks.

Contacts

Public
Rijnstate Ziekenhuis

wagnerlaan 55
Arnhem 6815 AD

NL
Scientific
Rijnstate Ziekenhuis

wagnerlaan 55
Arnhem 6815 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients over 18 years of age
Signed informed consent
Edge stenosis of the endograft in the SFA with a peak systolic velocity ratio (PSV ratio) of >2.5
Target vessel diameter > or equal to 4 mm and < or equal to 7 mm

Exclusion criteria

-Pregnancy or breast feeding women
-Known allergies or sensitivity to heparin, aspirin, other anticoagulant/antiplatelet therapies, -paclitaxel or contrast media that cannot be adequately pre-treated prior to index procedure
-Patient unsuitable for administration of contrast agent
-Stroke or heart attack within 3 months prior to enrollment
-Enrolled in another investigational drug, device or biologic study
-Any surgical procedure or intervention performed within 30 days prior to or post index procedure
-Failure to successfully cross the target lesion
-Angiographic evidence of severe calcification
-Dementia or altered mental status that would prohibit giving conscious informed consent

-Need for adjunctive major surgical or vascular procedures within one month
-Untreated flow-limiting aortoiliac occlusive disease
-Severe medical comorbidities (untreated CAD/CHF, severe COPD, metastatic malignancies, dementia etc.) or other medical condition that would preclude compliance with study protocol
-Any previously known coagulation disorder, including hypercoagulability

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2013
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Paclitaxel Drug Eluting Balloon (hereinafter referred as ''IN.PACT admiral DEB'') manufactured by Me
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-10-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-08-2016

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL44386.091.13

Study results

Date completed:	13-06-2018
Actual enrolment:	23