Prospective, multicenter Tack Optimized Balloon Angioplasty (TOBA) study for femoropopliteal arteries using the Tack-IT Endovascular Stapler.

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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-OMON41405

Source
ToetsingOnline

Brief title
The TOBA study.

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Atherosclerosis, Peripheral arterial disease.

Research involving
Human

Sponsors and support

Primary sponsor: Intact Vascular

Source(s) of monetary or material Support: Intact Vascular;Wayne;PA;USA

Intervention

Keyword: Atherosclerosis., Femoro-popliteal artery., Peripheral arterial disease., PTA and stenting.

Outcome measures

Primary outcome

Absence of need for target lesion revascularization during 30 days follow-up.

Absence of distal trombo-emblization during 30 days follow-up.

Technical success: <30% residual stenosis of the treated SFA after placement of

a Tack-IT ring during completion angiography.

Secondary outcome

Amputation free survival at 12 and 24 months follow-up.

Freedom from restenosis (>50%) at 12 and 24 months follow-up

Changes in ankle brachial index from baseline at 12 and 24 month follow-up.

Changes in Rutherford class from baseline at 12 and 24months follow-up.

All cause mortality at 12 and 24 months follow-up.

Study description

Background summary

Peripheral arterial disease affects between 3-7% of the population above the age of 75. Of these patients, 15-30% migth suffer from critical limb ischemia if peripheral arterial disease hasn't been treated. In most of the patients the obstruction is localized in the femoro-popliteal arteries. The results of percutaneous transluminal angioplasty (PTA) for long-segment (>10 cm) obstructions of the superficial femoral artery (SFA) arre rather disappointing with a one-years patency of 20-33%. This is mainly due to "elastic recoil" of the arterial wall post-PTA. Besides, the SFA is a dynamic artery and suffers from shortening, torsion and bending forces during movement of the leg and

especially the knee joint. In order to improve PTA results stents have been developped and used. Stents migth prevent elastic recoil post-PTA and can be used to tack intimal damage like dissections post-PTA. One of the major disavdantages of the use of stents in the dynamic SFA is the risk for stent fracture. Another drawback is intimal hyperplasia inside the stents, which might cause in-stent restenosis.
De Tack-IT Endovascular Stapler bestaat uit een zeer kort stent achtige frame (Tack ring genaamd) dat wel stent eigenschappen heeft om de rcoil tegen te gaan en de intima van de vaatwand te behandelen en vast te zetten, maar niet het nadeel heeft van de langere stents, zoals stentbreuk. Doordat de Tack-IT Endovascular Stapler zeer kort is (elke Tack ring is 6 mm lang), kan het ook worden gebruikt op het buigpunt van de arteria femoralis superficialis en de arteria poplitea (knie slagader).
De Tack-IT Endovascular Stapler zou dus het resultaat van PTA behandeling kunnen optimaliseren maar dan zonder de nadelen van de huidige stents. Hiermee zou het resultaat van PTA behandeling van de AFS kunnen worden verbeterd.

Study objective

De Tack-IT Endovascular Stapler consists of a very short stent-like frame (Tack ring or endovascular ring) which has the properties of a stent (to prevent elastic recoil and to treat intimal damage), but lacks the disadvantages of the usual longer stents, like stent fracture. The Tack-IT Endovascular Stapler is 6 mm long and can be used at the bending point of the superficial femoral artery and the popliteal artery.
De Tack-IT Endovascular Stapler could optimize the results of the current standard PTA treatment, but without the disadvantages of the usual stents. In that way it could lead to better results in the endovascular treatment of SFA obstructions. Efficacy and safety of the device will be determined in this study.

Study design

Prospective, single-arm, non-randomized, non-blinded study. All patients will be treated with the Tack-IT Endovascular Stapler.

Intervention

In patients who meet the inclusion criteria (and don't have any exclusion criterium) Tack-rings will be placed in the SFA with use of the Tack-IT Endovascular Stapler. A maximum of 8 Tack-rings will be placed.

Study burden and risks

Patients in this study will have similar work-up as all other (non-study) patients before PTA of the SFA in our hospital. The follow-up scheme is also

similar to the regular follow-up post PTA of the SFA. The PTA procedure itself will also be similar to non-study patients. The only difference comparing to standard PTA treatment of the SFA is the fact that no long stent will be used, but the short Tack-IT rings. Placement of the Tack-IT rings is quite similar to the placement of regular stents, however, the Tack-IT rings are much shorter compared to the regular stents. So far, no device related complications have been mentioned with the Tack-IT device. CE approval has been obtained for the Tack-IT device.

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

General inclusion criteria:
Age >18 years.

Rutherford classification 2, 3 or 4 concerning peripheral arterial disease.
ABI < 0.90
Angiographic inclusion criteria:
Stenosis of the SFA >70%
Total length of the SFA obstruction <10 cm
Possibility to pass the SFA obstruction with guidewire
Residual stenosis of <30% post-PTA
No aneurismal SFA disease, nor acute thrombosis
Diameter of the treated SFA in between 2.5 and 5.5 mm
Run off by at least one crural artery

Exclusion criteria

Rutherford classification 5 or 6.
Former treatment of the SFA.
Former femoro-popliteal bypass.
Planned amputation of the ipsilateral leg.
Infection of the ipsilateral leg.
Significant obstruction of the inflow or outflow arteries of the ipsilateral leg without treatment.
Acute thrombosis
Immune compromised patient
Know coagulopathy, thrombocytopenia, INR > 1.5
Myocardial infarction 30 days prior to treatment
Stroke 3 months prior to treatment
Renal insufficiency (kreat >220 umo/l)
Pregnancy or breast feeding
Number of needed Tacks will be >8
Severe, circumferential calcification of the target lesion >5 cm.
Subject requires treatment of tibial or outflow vessels at the index procedure.
Subject has a known hypersensitivity or contraindication to nitinol.
Subject to return for 24 Month Visit has been previously reported as having a non-patent target lesion or a target lesion revascularization.

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):	09-01-2013
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Tack-IT Endovascular Stapler
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-11-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-08-2015
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	NL41933.100.12