Tack Optimized Balloon Angioplasty Study for the Superficial Femoral and Proximal Popliteal Arteries Using the Tack Endovascular System. (TOBA II)

Published: 15-04-2016
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To compare the safety and efficacy of the Tack Endovascular System* in subjects with peripheral artery disease (PAD) to a pre-defined performance goal (PG).

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

Summary

ID

NL-OMON43996

Source
ToetsingOnline

Brief title
The TOBA II 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 (sponsor)

Intervention

Keyword: dissection, peripheral artery disease, PTA and stenting, Superficial Femoral / Proximal Popliteal Arteries

Outcome measures

Primary outcome

Safety:

Freedom from the occurrence of any new-onset major adverse event(s) (MAEs) defined as index limb amputation (above the ankle), CEC adjudicated clinically-driven target lesion revascularization (CD-TLR), or all-cause death at 30 days.

Efficacy:

Primary patency defined as freedom from CEC adjudicated clinically-driven target lesion revascularization (CD-TLR) and freedom from core lab adjudicated duplex ultrasound derived binary restenosis at 12 months (defined as PSVR >2.5).

Secondary outcome

Device Success:

Successful deployment of the Tack(s) at the intended target site(s) and successful withdrawal of the delivery catheter from the introducer sheath. If the study device is introduced but the subject does not receive a Tack due to user error and not a device malfunction, this device will not be included in the device success assessment.

Procedural Success:

Demonstrated vessel patency (<30% residual DS, by visual estimate) without the

use of a bailout stent or the occurrence of MAE upon completion of the index procedure.

In addition, the following observational endpoints will be assessed at various time points through 24 months (See Section 8.1 Time and Events Schedule):

All cause death

Amputation of the target limb (above the ankle)

Clinically-driven target vessel revascularization (CD-TVR)

Clinically-driven target target lesion revascularization

Target vessel revascularization (TVR)

Target lesion revascularization (TLR)

Changes from baseline in Rutherford Classification

Changes from baseline in Ankle Brachial index (ABI) measurement

Changes from baseline in Peripheral Artery Questionnaire (PAQ)

Changes from baseline in the EQ-5D-3L quality of life questionnaire

Changes from baseline in the Walking Impairment Questionnaire (WIQ)

Tack integrity via X-ray

Duplex Ultrasound (DUS) derived lesion and vessel patency

Study description

Background summary

To fully understand the impact of post-PTA dissections, investigation is required on their associated potential clinical implications. Because of higher incidence of complications due to dissections, their impact on clinical outcome has been an important issue in percutaneous coronary interventions. More severe

dissections seem to be associated with higher restenosis rates and early occlusions. The most comprehensive assessment of clinical implications in the peripheral vasculature was the previously discussed in the THUNDER study. Angiographic analysis of study patients included angiograms from before and after the intervention and from the 6-month follow-up. The primary clinical outcome was TLR at 6- and 24- month time points. The parameters assessment were late lumen loss (LLL), minimum lumen diameter (MLD) and an area analysis to evaluate the entire longitudinal luminal area of the vessel dilated. There were no significant differences in the post-procedure angiographic parameters between patients with grades A or B dissection vs. grade C, D, or E (although the degree of residual stenosis (Narrowing) tended to be larger with higher grade dissections).
The THUNDER study concluded that untreated dissections were observed to be correlated with increased complications and with decreased long-term patency. For all dissection grades, clinical implications were noted in patients with observed dissections. To further understand the implications, the literature results were reviewed and compiled to compare to the extent possible the clinical/angiographic results of PTA with no post-procedure dissections (from general literature references) to those of post-PTA dissection (from the THUNDER Trial) in the femoropopliteal arteries. Only one time period had defined data for both subsets (6 months).
The results in suggest that even with low grade dissections (Type A/B) clinical implications may be observed with lower patency rates than those observed for PTA and higher rates of TLR when compared to PTA without dissections. While these results are more pronounced for C/D/E dissections, the clinical impact of all dissections is notable. Primary patency was lower and target lesion revascularization higher for the patient population with observed dissections. Based on the clinical and literature reported data indicative of an under-reporting of higher grade dissections and the clinical links to observed lower patency rates, there exists a clinical need to provide for focal treatment of post-PTA non-flow-limiting dissections in addition to those that are flow-limiting. The Tack Endovascular System is designed to provide a treatment option for all grade dissections.

Study objective

To compare the safety and efficacy of the Tack Endovascular System* in subjects with peripheral artery disease (PAD) to a pre-defined performance goal (PG).

Study design

This is a prospective, multi-center, single-arm, non-blinded study designed to investigate the safety and efficacy of the Tack Endovascular System*.

Intervention

The Tack Endovascular System* is intended for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 2.5mm to 6.0mm for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissection(s) type(s) A through F.

Study burden and risks

Minimal extra risk associated with study assessments since most assessments are also performed per standard care.

Additional "burden" is related to increased follow-up visits, x-ray at 12 months for subjects implanted with Investigational Product and all subjects are asked to complete 3 (relative easy) questionnaire at FU visits.

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

CLINICAL INCLUSION CRITERIA;1. * 18 years
3. Target limb requires no additional treatment aside from the target lesion and ipsilateral iliac artery
6. Rutherford Classification 2, 3 or 4
8. Eligible for standard surgical repair, if necessary
9. Subject is ambulatory (assistive devices such as a cane or walker is acceptable);ANGIOGRAPHIC INCLUSION CRITERIA;1. Reference vessel diameter is between 2.5 mm and 6.0 mm, inclusive (by visual estimate)
2. Ability to cross a guidewire (antegrade) through target lesion
3. Has a de novo or non-stented restenotic target lesion indicated for PTA treatment with a standard or FDA-approved Lutonix drug-coated balloon catheter that meets the following criteria below:
a. 70% to 99% stenosis with a total lesion length of *20mm and *150mm in length (by visual estimate) or
b.100% occluded with a total lesion length *100mm (by visual estimate)
c. A non-stented restenotic lesion must meet the following criteria:
i. Meets criteria 3a and 3b
ii. No part of the target lesion has been previously treated with a drugcoated balloon
iii. No part of the target lesion has had more than 2 previous PTA failures
iv. >90 days from most recent angioplasty treatment
4.Target lesion is in the superficial femoral artery (SFA) and/or proximal popliteal artery (above the knee joint) defined as: located *1 cm below the common femoral artery (CFA) bifurcation to the distal segment of the proximal popliteal (P1) artery at the superior end of the patella

Exclusion criteria

CLINICAL EXCLUSION CRITERIA;1. Rutherford Classification 0, 1, 5 or 6
2. Is pregnant or refuses to use contraception through the duration of the study
3. Previous infrainguinal bypass graft in the target limb
8. Prior coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) procedure within 30 days prior to the index procedure or planned CABG/PCI within 30 days after the index procedure
9. Any other previous or planned surgical or endovascular procedure (not including diagnostic procedures) within 14 days prior to or 30 days post index procedure
10. Planned atherectomy, cryoplasty, stenting or any other treatment (with the exception of a crossing device) of the target lesion other than PTA during the index procedure
16. Requires treatment of tibial or outflow vessels at the index procedure, which include the P2 and P3 segments of the popliteal artery and the tibioperoneal vessels.
18. Participating in another ongoing investigational clinical trial that has not completed its primary endpoint;ANGIOGRAPHIC EXCLUSION CRITERIA:;1. Retrograde access through target

limb
2. Acute vessel occlusion or acute or sub-acute thrombosis in target lesion
3. Subject has significant stenosis (*50% stenosis) or occlusion of ipsilateral inflow iliac artery not successfully treated (<30% residual DS and without complication) prior to PTA of target vessel
4. Angiographic evidence of calcification severe enough that it renders the target lesion non-dilatable and/or has circumferential calcification
5. The target lesion shows no dissections after PTA
6. Presence of residual diameter stenosis *30% after PTA (based on visual estimate)
7. Non-target limb requiring any vascular treatment at time of index procedure
8. Previously implanted stent in the target vessel

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):	15-04-2016
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Tack endovascular System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-04-2016
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-10-2016
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
ClinicalTrials.gov	NCT02522884
CCMO	NL55439.100.15