Prospective, Randomized, Controlled, Multicentre, Open Study Releas of Paclitaxel during PTA versus PTA alone for the treatment of de-novo occluded, stenotic or reoccluded, restenotic superficial femoral (SFA) or popliteal arteries.

Published: 13-03-2012
Last updated: 27-04-2024

The study investigates the inhibition of restenosis by the Paclitaxel-eluting PTA balloon Freeway versus stenting-PTA or PTA alone in the treatment of de-novo occluded, stenotic or reoccluded, restenotic superficial femoral (SFA) or popliteal...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON35958

Source
ToetsingOnline

Brief title
FREERIDE-STUDY

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
narrowing of the bloodvessel, stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Eurocor GmbH
Source(s) of monetary or material Support: De sponsor stelt het materiaal ter beschikking

Intervention

Keyword: Angioplasty, Balloon catheter, Freeway, Paclitaxel

Outcome measures

Primary outcome

Rate of clinically driven target lesion revascularization (TLR) at 6 months

Secondary outcome

1. Technical success defined as the rate of successfully performed index

procedures after wire passage

2. Late lumen loss, i.e. the difference between the minimum lumen diameter

after intervention and during the follow-up at 6 months determined by

angiography

3. Clinical success defined as technical success without the occurrence of

serious adverse events during procedure

4. Ankle-Brachial Index improvement of >= 0.1 (ABI before procedure compared

with ABI at discharge and at 6, 12 (and 24) months

5. Primary and secondary patency rate defined as <50% diameter reduction and

peak systolic velocity <2.4 at 6, 12 (and 24) months

6. Change in WIQ i.e. walking impairment questionnaire from pre-intervention to

6, 12 (and 24) months follow-up improvement of walking distance before

procedure compared with walking distance at discharge and at 6 and 12 months

(if Treadmill test is available)

7. Rate of minor and major complications at 6 and 12 (and 24) months

8. Change in Rutherford classification grades of chronic limb ischemia from

pre-intervention to 6, 12 (and 24) months follow-up.

9. Rate of clinically driven target lesion revascularization (TLR) at 12 (and

24) months

Study description

Background summary

Although the immediate outcome of angioplasty of SFA and popliteal arteries are generally satisfactory (success rate around 90%), the attempt to restore normal flow using this technique often fails in the medium term (with a failure rate of over 50% in some series) and the reason for this is restenosis.

Study objective

The study investigates the inhibition of restenosis by the Paclitaxel-eluting PTA balloon Freeway versus stenting-PTA or PTA alone in the treatment of de-novo occluded, stenotic or reoccluded, restenotic superficial femoral (SFA) or popliteal arteries.

Study design

Prospective, Randomized, Controlled, Multicentre, Open Study

Intervention

PTA with paclitaxel-eluting PTA balloon Freeway or stenting-PTA or PTA alone.

Study burden and risks

The risks involved with undergoing an angiogram.

Contacts

Public
Eurocor GmbH

Rheinwerkallee 2
D-53227 Bonn
DE
Scientific
Eurocor GmbH

Rheinwerkallee 2
D-53227 Bonn
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with symptomatic ischemia, requiring treatment of SFA or popliteal artery

Exclusion criteria

Pregnancy, aneurisma disease of the abdominal aorta, iliac or popliteal arteries, contraindication for anti platelet therapy, stroke<3months, prior surgery target lesion,

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Paclitaxel-eluting PTA balloon Freeway
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-03-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL35524.075.11