Prospective, Non-randomized, Multicentre, Observational Registry To confirm the performance of Misago Peripheral Self-Expanding Stent System for the Treatment of Occluded or Stenotic Superficial Femoral or Popliteal Arteries.

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To confirm the performance and long term safety of MisagoPeripheral Self-Expanding Stent System for the treatment ofoccluded or stenotic Superficial Femoral or Popliteal arteries in thedaily practice

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON32020

Source
ToetsingOnline

Brief title
Misago-2 registry

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
blockage of arteries, occlusion, stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Terumo
Source(s) of monetary or material Support: Terumo

Intervention

Keyword: efficacy, Femoral popliteal arteries, Misago-stent, occlusion, stenosis

Outcome measures

Primary outcome

Absence of clinically driven target lesion revascularization at 6 and 12 months

Secondary outcome

1. Technical success defined as a successful access and deployment of the

device with recanalisation determined by

less than 30% residual stenosis by angiography at the baseline procedure

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

serious adverse events during procedure

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

with ABI at discharge and at 6 and 12

months)

4. Primary and secondary patency rate (if duplex ultrasound available) defined

as <50% diameter reduction and peak

systolic velocity <2.4

5. Improvement of walking distance before procedure compared with walking

distance at discharge and at 6 and 12 months (if Treadmill test available)

6. Clinically driven Target Vessel Revascularization at 6 and 12

months

7. Major complications at 6 and 12 months, including amputation of the distal

part of the foot, the leg below the knee and the thigh

8. Vascular complications

9. Bleeding complications

10. The Rutherford classification of chronic limb ischemia at discharge and at

6 and 12 months post procedure

11. Stent Fracture at 6 and 12 months post procedure

Study description

Background summary

Currently, interventional procedures (balloon angioplasty and stenting) are the first treatment to be proposed for most patients who have peripheral vascular disease.This kind of pathology is frequently seen in elderly patients (up to 20% of the population above 65 years).
MISAGO is a new generation nitinol self expandable stents used for the treatment of occluded superficial femoral artery (SFA) and Popliteal artery.
The product is CE marked.

Study objective

To confirm the performance and long term safety of Misago Peripheral Self-Expanding Stent System for the treatment of occluded or stenotic Superficial Femoral or Popliteal arteries in the daily practice

Study design

Non-randomized, prospective, multicentre, observational registry.

Study burden and risks

The Registry only documents the treatment of the patient, therefore it does not

present any risk in addition to the standard risk of the procedure.

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

Patients with documented symptomatic occlusion and/or >70%
stenosis of SFA or popliteal artery in one or both legs;1. Patients with symptomatic one or two legs ischemia, requiring
treatment of SFA or popliteal artery (2 or more by Rutherford
classification)
2. Single lesions per leg with recoiling/dissection/restenosis after
balloon angioplasty or de novo lesions with stenosis or occlusion,
which can be covered by maximum two stents
3. Target vessel reference diameter >=4mm and <=6mm (by visual

estimate)
4. Target lesion length should consider that maximum two Misago stents can be implanted per lesion with recommended overlap 2 mm
5. At least one patent (less than 50% stenosis) tibioperoneal run-off vessel confirmed by baseline angiography
6. Patient is suitable candidate for femoral-popliteal artery bypass surgery

Exclusion criteria

Patient with any of the following should be excluded:
1. Pregnancy
2. Previous bypass surgery or stenting in the target vessel
3. Scheduled staged procedure of multiple lesions within the ipsilateral iliac or popliteal arteries within 30 days after index procedure
4. Co-existing aneurismal disease of the abdominal aorta, iliac or popliteal arteries
5. Acute thrombophlebitis or deep venous thrombosis
6. Hemodynamic instability
7. Untreated inflow disease of the ipsilateral pelvic arteries (more than 50 percent stenosis or occlusion),
8. Significant gastrointestinal bleeding or any coagulopathy that would contraindicate the use of anti-platelet therapy
9. Known

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2008

Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Stent (CE number 0197)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-06-2008
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL21681.094.08