

Prospective, non-randomised, multi-centre, observational study to confirm the performance of Misago® peripheral self-expanding stent system for the treatment of occluded or stenotic superficial femoral or popliteal arteries

Submission date 08/05/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/06/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/04/2011	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Vladimir Borovicanin

Contact details
Terumo Europe N.V.
European Clinical Division
Research Park Zone 2, Haasrode
Interleuvenlaan 40
Leuven
Belgium
B-3001
+32 (0)16 38 14 54
vladimir.borovicanin@terumo-europe.com

Additional identifiers

Protocol serial number

T108E2

Study information

Scientific Title**Acronym**

MISAGO 2

Study objectives

The objective of the registry is 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 daily practice.

The rationale is that the Misago® self-expandable stent would show similar characteristics in comparison with new generation of nitinol self-expanding stents when tested on larger number of subjects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. Freiburger ethik kommission International (Germany) on the 3rd March 2008
2. Ethik Kommission Fachbereich Medizin der Johann Wolfgang Goethe - Universitaet Frankfurt a Mein (Germany) on the 29th April 2008
3. Ethik Kommission der Aerztekammer Westfalen-Lippe und der Medizinischen Fakultaet der Westfaelishen Wilhelms-Universitaet Muenster (Germany) on the 24th April 2008

All other participating countries have submitted to all participating hospital Ethics Committees wherever such requirement exists prior to enrolment of patients. Last site start up expected July 2008.

Primary study design

Observational

Study design

Observational, single arm, prospective multi-centre study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Occluded or stenotic superficial femoral and/or popliteal arteries

Interventions

Observational collection of routine hospital practice, clinical/telephone follow-up and monitoring of all serious adverse events* and medication regiments.

*An adverse event is considered serious if the event led, or might have led, to one of the following outcomes:

1. Death of a patient, USER or other person
2. Serious deterioration in state of health of a patient, USER or other person

A serious deterioration in state of health can include:

1. Life-threatening illness
2. Permanent impairment of a body function or permanent damage to a body structure
3. A condition necessitating medical or surgical intervention to prevent 1. or 2.
4. Any indirect harm as a consequence of an incorrect diagnostic or in vitro diagnostic medical devices (IVD) test results when used within manufacturer's instructions for use
5. Foetal distress, foetal death or any congenital abnormality or birth defects

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Misago® peripheral self-expanding stent

Primary outcome(s)

Absence of clinically driven target lesion revascularisation at 6 and 12 months.

Key secondary outcome(s)

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 (ABI) improvement of greater than or equal to 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 less than 50% diameter reduction and peak systolic velocity less than 2.4
5. Improvement of walking distance at discharge and at 6 and 12 months compared with walking distance before procedure (if treadmill test available)
6. Clinically driven target vessel revascularisation 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 ischaemia at discharge and at 6 and 12 months post-procedure
11. Stent fracture at 6 and 12 months post-procedure

Completion date

01/10/2009

Eligibility

Key inclusion criteria

Patients must fulfil all of the following criteria:

1. Patients with symptomatic one or two legs ischaemia, requiring treatment of superficial femoral artery (SFA) or popliteal artery (two 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 greater than or equal to 4 mm and less than or equal to 6 mm (by visual estimate)
4. Target lesion length should consider that maximum two Misago® stents can be implanted per lesion with recommended overlap of 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
7. Aged 18 years or older, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Patients 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. Haemodynamic instability
7. Untreated inflow disease of the ipsilateral pelvic arteries (more than 50% stenosis or occlusion)
8. Significant gastrointestinal bleeding or any coagulopathy that would contraindicate the use of anti-platelet therapy
9. Known intolerance to study medications, contrast agents or nitinol

Date of first enrolment

01/04/2008

Date of final enrolment

01/10/2009

Locations

Countries of recruitment

United Kingdom

Austria

Belarus

Belgium

Czech Republic

Denmark

France

Germany

Greece

Israel

Italy

Netherlands

Spain

Sweden

Study participating centre

Terumo Europe N.V.

Leuven

Belgium

B-3001

Sponsor information

Organisation

Terumo Europe N.V. (Belgium)

ROR

<https://ror.org/043vk3t22>

Funder(s)

Funder type

Industry

Funder Name

Terumo Europe N.V. (Belgium) (ref: T108E2)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No