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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

Registration date
05/06/2008

Overall study status
Completed

Last Edited
21/04/2011

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 Komission Fachbereich Medizin der Johann Wolfgang Goethe - Universitaet Frankfurt a Mein (Germany) on the 29th April 2008
3. Ethik Kommission der Aerztekammer Westfallen-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.

Study design
Observational, single arm, prospective multi-centre study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/04/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

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
Austria

Belarus

Belgium

Czech Republic

Denmark

France

Germany

Greece

Israel

Italy

Netherlands

Spain

Sweden

United Kingdom

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Sponsor information

Organisation
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Sponsor type
Industry

Website
http://www.terumo-europe.com

ROR
https://ror.org/043vk3t22

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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