ISRCTN57930977 https://doi.org/10.1186/ISRCTN57930977

Safety and efficacy of the Misago® peripheral self-expanding stent system in real-world patients

Submission date 21/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/11/2009	**Overall study status** Completed	
Last Edited 12/04/2017	**Condition category** Circulatory System	

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 Medical and 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
T112E2

Study information

Scientific Title
Prospective, non-randomised, multicentre, observational study to further support safety and efficacy of the Misago® peripheral self-expanding stent system in real-world patients

Acronym
E-MISAGO

Study objectives
The objective is to further support safety and efficacy of the Misago® peripheral self-expanding stent system in real-world patients.

The rationale for this study is to create - on the largest scale ever - a window into the real-world of patients treated with the Misago® Stent (as one of the newest generation nitinol self-expanding stents).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of UZ Gent (Belgium) approved on 06/08/2009. 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 April 2010.

Primary study design
Observational

Study design
Observational non-randomised single-arm prospective multicentre study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Occluded or stenotic iliac, superficial femoral and/or popliteal arteries

Interventions
Observational collection of routine hospital practice including 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 point 1 or 2 immediately above

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
Other

Phase
Not Applicable

Primary outcome(s)
1. Safety: Freedom from all cause death, index limb amputation and target lesion revascularisation through 30 days
2. Efficacy: Target vessel patency defined as freedom from target lesion revascularisation caused by greater than 50% stenosis at 1 year

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, measured before discharge
2. Clinical success defined as technical success without the occurrence of serious adverse events during procedure, measured before discharge
3. Ankle Brachial Index improvement at 30 days and 1 year
4. Improvement of the Rutherford Index at 30 days and 1 year
5. Walking distance at 30 days and 1 year compared with walking distance before procedure (if Treadmill Test available)
6. Clinically driven Target Vessel Revascularisation at 1 year
7. Major complications at 1 year, (death (CV cause), index limb amputation and target lesion revascularisation within 1 year
8. Vascular complications, measured before discharge
9. Bleeding complications, measured before discharge
10. Improvement of quality of life at 30 days and 1 year

Completion date
01/11/2011

Eligibility

Key inclusion criteria
Patients aged greater than 18 years, either sex, that as per hospital practice are treated with a self-expanding nitinol stent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2009

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
United Kingdom

Austria

Belgium

Czech Republic

Denmark

Estonia

France

Germany

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: T112E2)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration