SafePass: A prospective, non-randomized, multi-center, open-label, clinical investigation to assess the safety and technical performance of the Emboliner
embolic protection catheter.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48609

Source
ToetsingOnline

Brief title
SafePass.2

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Embolism and thrombosis

Synonym
cerebral and non-cerebral embolism; blocking of blood flow

Health condition

cardiac valve disorders

Research involving
Human

Sponsors and support

Primary sponsor: Emboline Inc.
Source(s) of monetary or material Support: industry

Intervention

Keyword: -Catheter, -Embolic protection, -TAVR procedure

Outcome measures

Primary outcome

Safety:

Incidence of 30-day MACCE, defined as the composite of death, stroke, or Stage

3 acute kidney

injury (AKI)

Performance:

Technical performance (technical success) is defined as the ability to

successfully (without device malfunction):

* Ability to access the aortic arch with the delivery catheter;

* Ability to position the Emboliner across the aortic arch

* Ability to retrieve and remove the Emboliner without damage (as reported by

the Investigator)

Secondary outcome

* Incidence of in-hospital investigational device-related serious adverse events

* Incidence of investigational device-related serious adverse events at 30 days

* Incidence of adverse procedure (non-device) related events at 30 days

* Minimal interference to the TAVR procedure as determined by the investigator

* User feedback on ease of preparation, delivery, placement, and control of the

device during

the procedure

* Presence of captured debris in the Emboliner filter after retrieval

* Histopathological characterization of captured debris size, volume,

morphology and

composition

Study description

Background summary

Heart valve replacement by [transcatheter aortic valve replacement (TAVR)] procedure is commonly used to in order to repair the valve without removing the old, damaged valve.
A known complication of similar procedures is the dislodging of embolic particles. Those particles may include thrombus, valvular tissue and foreign material. Once entered the bloodstream, those might lead to neurological and neurocognitive deficits, stroke or death. The Emboliner embolic protection catheter is a temporarily-implanted aortic embolic filter for use during cardiology procedures, such as TAVR. The filter of the Emboliner is intended to stop dislodged embolic particles from entering the bloodstream.

Study objective

The primary objectives are to evaluate preliminary data on the safety and performance of the
Emboliner embolic protection catheter.
Safety:
Assess procedural safety risks
Performance:

Assess the technical performance in conjunction with a TAVR procedure.

Study design

A safety and performance study, structured as a non-randomized, multi-center, open-label,
prospective interventional clinical investigation in subjects who are candidates for the
use of the Emboliner embolic protection catheter during TAVR.

Intervention

Screening, procedure, in-hospital safety assessment, 30-day telephone follow-up. Interim analysis for in-hospital device-related adverse events by the review committee after 10patients.

-Screening procedures
* Verification of conformance to all eligibility criteria
* Informed consent process
* Complete medical history
* Physical examination (incl. BP, Heart Rate, ECG)
* CBC with differential, platelet count, serum creatinine, and troponin or CK/CK-MB
* Female candidates must have negative pregnancy test, or other evidence of not being pregnant

- Pre-, intra-, and post-operative medication
Standard medication for transcatheter TAVR procedures for the investigation site will be used
and documented in the appropriate section of the Case Report Form.

- Delivery, Positioning and Retrieval of the Emboliner
The procedure for preparation, delivery, positioning and retrieval of the Emboliner shall be
conducted in accordance with the Emboliner IFU, LBL-0385.

- Pre-discharge evaluation
* Evaluation for in-hospital device-related adverse events
* Assessment of access site complications
* Documentation of concomitant medication

- Post-implant evaluation at 30 days (±7 days) * telephone follow-up acceptable
* Documentation of concomitant medication
* Evaluation for predefined MACCE endpoints (death, stroke and Stage 3 AKI)
* Evaluation for adverse events

Study burden and risks

When participating in the study the only procedures that differ from standard care are the use of the Emboliner embolic protection catheter during the procedure and the study related phone call 30 days after the procedure is additional to standard care. These procedures have a minor impact on the patient.
The potential benefits of the Emboliner have been determined
to outweigh its potential risks as documented in RM-0310, Risk Management Plan/Report for the
Emboliner. In addition, the Investigator*s Brochure includes a comprehensive overview of all preclinical
testing that was conducted on the Emboliner system.

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

1. The patient must be 18 years and older.
2. The patient must meet the indications for the TAVR procedure.
3. The patient is willing to comply with protocol-specified follow-up evaluations.
4. The patient has been informed of the nature of the study, agrees to its provisions and has provided written informed consent, approved by the appropriate Medical Ethics Committee (EC)

Exclusion criteria

1. Patients with an ascending aortic diameter >40 mm, or a descending aorta >27 mm.
2. Patients with the linear distance from the femoral access site to the aortic valve root greater
than 85 cm.
3. Patients not undergoing TAVR via the trans-femoral route.
4. Patients that are contraindicated for anticoagulant and/or antiplatelet therapy.
5. Patients with uncorrected bleeding disorders.
6. Pregnant or nursing subjects, or subjects who intend to become pregnant during the term of
the study.
7. Patients with known diagnosis of acute myocardial infarction (AMI) within 30 days preceding
the index procedure (according to definition) or AMI >30 days preceding the index procedure, in whom either troponin levels, or CK (creatine kinase) and CK-MB (creatine kinase-Muscle Brain) have not returned to within normal limits at the time of procedure.
8. Patients with known other mental or physical illness or known history of substance abuse that may cause non-compliance with the protocol, confound the data interpretation, or is associated with a life expectancy of less than one year.
9. Patients with severe allergy to heparin or known hypersensitivity or contraindication to aspirin, heparin, bivalirudin, clopidogrel, and/or contrast sensitivity that cannot be adequately pre- medicated.
10. Patients with a history of a stroke or transient ischemic attack(TIA) within the prior 6 months.
11. Patients with an active peptic ulcer or history of upper gastrointestinal(GI) bleeding within the
prior 3 months.
12. Patients with renal failure (estimated Glomerular Filtration Rate <30 mL/min, calculated from
serum creatinine by the Cockcroft-Gault formula).
13. Patients with hypercoagulable states that cannot be corrected by additional periprocedural
heparin.
14. Patients presenting with cardiogenic shock or severe hypotension (systolic blood pressure

<90 mm Hg) at the time of the index procedure.
15. Patients with severe peripheral arterial disease that precludes delivery sheath vascular access, or whose vascular anatomy is unable to accommodate a 9.5-Fr sheath.
16. Patients who have a planned treatment with any other investigational device or procedure
during the study period.
17. Patients planned to undergo any other cardiac surgical or interventional procedure (e.g., concurrent coronary revascularization) during the TAVR procedure, within two (2) weeks prior to the TAVR procedure, or 30 days after the TAVR procedure.
18. Patients with porcelain aorta, asymmetrical or sharp aortic calcifications, high grade aortic
stenosis, or torsion of the aorta.
19. Emergency patients.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Generic name:	Emboliner embolic protection catheter
Registration:	No

Ethics review

Approved WMO

Date:	04-04-2018

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-02-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL63175.041.17