A Prospective, Randomized Evaluation of the TriGuard* HDH Embolic DEFLECTion Device during Transcatheter Aortic Valve Implantation

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To assess the safety, efficacy, and performance of the TriGuard HDH embolic deflection device in patients undergoing transcatheter aortic valve implantation (TAVI), in comparison with patients undergoing unprotected TAVI.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON40785

Source
ToetsingOnline

Brief title
DEFLECT III

Condition

- Cardiac valve disorders

Synonym
brain infarction, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Keystone Heart

Source(s) of monetary or material Support: Keystone Heart

Intervention

Keyword: Aortic Valve replacement, CVA, Embolic filter, TIA

Outcome measures

Primary outcome

The overall occurrence of the composite in-hospital procedural safety endpoint will be reported by treatment arm using descriptive statistics (frequencies, percentages, and two-sided exact 95% confidence intervals) in the Intention to Treat (ITT) population of evaluable subjects (Roll-In patients are excluded).

No formal hypothesis testing will be performed. For safety endpoint events occurring in the Intervention and Roll-In groups, relationship to the investigational device/investigational procedure (as determined by an independent Clinical Events Committee) will also be reported.

Thirty-four (34) evaluable subjects in each treatment arm are expected to be sufficient to provide information regarding the safety, performance, and efficacy of the TriGuard HDH device relative to unprotected TAVI. An interim analysis will be performed after 20 subjects have been enrolled in each treatment arm (40 evaluable subjects total). The study will continue to enroll until 4±2 day postprocedural DW MRI data is available for 34 subjects in each treatment arm (68 evaluable subjects total). The sample size has been increased to 86 evaluable subjects to account for an expected 20% loss to DW MRI follow-up.

As a secondary analysis, the primary endpoint will also be reported in the Per Protocol (PP) population of evaluable subjects (Roll-In patients are excluded).

The PP population is defined as all subjects in whom no major protocol deviations (i.e., failure to obtain informed consent, failure to adhere to study eligibility criteria, or failure to use the TriGuard HDH in accordance with the Instructions for Use) are recorded.

Secondary outcome

All secondary endpoints will be reported by treatment group in the Intention To Treat (ITT) Population of evaluable subjects (Roll-In patients are excluded) using descriptive statistics. No formal hypothesis testing will be performed. Statistics for continuous variables will include mean, median, standard deviation, minimum, maximum, and sample size for each treatment group, and two-sided exact 95% confidence intervals. Binary variables will be summarized using frequencies, percentages, and two-sided exact 95% confidence intervals. For time-to-event data, Kaplan-Meier estimates at the indicated time points will be displayed along with two-sided exact 95% confidence intervals.
As additional analysis, all secondary endpoints will be evaluated in the PP population of evaluable subjects.

Study description

Background summary

The incidence of stroke and subclinical cerebral ischemic lesions, and their association with postprocedural neurological deficits, indicate that methods to prevent or reduce cerebral embolization are vital to optimizing TAVI procedures and improving the outcomes of patients with severe aortic stenosis. The first generation TriGuard device has been demonstrated to safety reduce the total cerebral ischemic lesion volume after TAVI compared with historical controls. This prospective, randomized trial will provide more comprehensive evaluation of the safety, efficacy, and performance of the TriGuard HDH device compared

with a concurrent active control of unprotected TAVI. By employing standardized imaging acquisition and analysis parameters and detailed neurocognitive testing, the DEFLECT III trial will also advance the understanding of subclinical neurological events and their relationship with neurocognitive function in patients undergoing cardiovascular interventions.

Study objective

To assess the safety, efficacy, and performance of the TriGuard HDH embolic deflection device in patients undergoing transcatheter aortic valve implantation (TAVI), in comparison with patients undergoing unprotected TAVI.

Study design

This prospective, randomized, multicenter, non-powered, safety, efficacy, and performance trial will enroll up to 86 evaluable subjects and up to 15 roll-in subjects at up to 15 investigational sites in Europe and Israel.
Subjects with indications for TAVI and who meet study eligibility criteria will be randomized 1:1 to one of two treatment arms:
• Intervention - TAVI with the TriGuard HDH embolic deflection device
• Control - standard unprotected TAVI
Prior to the first evaluable subject, each investigational site without prior experience with the TriGuard device (minimum of 3 prior cases) will enroll up to 1 roll-in subject, all of whom will undergo TAVI with the TriGuard HDH device. Investigational sites with >=3 prior TriGuard cases may choose to enroll 1 roll-in subject at the discretion of the site principal investigator.
All subjects will be followed clinically in-hospital and at 30 days, undergo diffusion-weighted MR imaging at 4±2 days and at 30±7 days post-procedure, and undergo neuropsychological testing pre- and post-procedure and at 30 (±7) days.

Intervention

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Study burden and risks

The known risks for TAVI are applicable, besides the potential of local vessel damage due to manipulation of the device in
the aortic arch and manufacturing problems of the device which may lead to unforeseen complications. The benefit would
be the prevention of cerebral embolsim during the TAVI 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

1. The patient is a male or non-pregnant female >=18 years of age
2. Patient meets indications for TAVI
3. The patient is willing to comply with protocol-specified follow-up evaluations

Exclusion criteria

1. Patients undergoing TAVI via the trans-axillary, trans-subclavian, or trans-aortic route
2. Patients undergoing TAVI via the transapical approach due to friable or mobile atherosclerotic plaque in the aortic arch
3. Pregnant or nursing subjects and those who plan pregnancy in the period up to 1 year following index procedure. Female subjects of child-bearing potential must have a negative

pregnancy test done within 7 days prior to index procedure per site standard test
4. Patients with known diagnosis of acute myocardial infarction (AMI) within 72 hours preceding the index procedure (according to definition) or AMI >72 hours preceding the index procedure, in whom CK and CK-MB have not returned to within normal limits at the time of procedure.
5. Patients who are currently experiencing clinical symptoms consistent with new-onset AMI, such as nitrate-unresponsive prolonged chest pain
6. Patients with a history of bleeding diathesis or coagulopathy or patients in whom anti-platelet and/or anticoagulant therapy is contraindicated, or who will refuse transfusion
7. 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
8. Patients with severe allergy to heparin or known hypersensitivity or contraindication to aspirin, heparin/bivalirudin, clopidogrel, nitinol, stainless steel alloy, and/or contrast sensitivity that cannot be adequately pre-medicated
9. Patients with a history of a stroke or transient ischemic attack (TIA) within the prior 6 months
10. Patients with an active peptic ulcer or history of upper gastrointestinal (GI) bleeding within the prior 6 months
11. Patients with renal failure (estimated Glomerular Filtration Rate [eGFR] <30 mL/min, calculated from serum creatinine by the Cockcroft-Gault formula)
12. Patients with hepatic failure (Child-Pugh class C)
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
16. Patients with a heavily calcified or severely atheromatous aortic arch
17. Patients with an innominate artery ostium diameter <11 mm
18. Patients with a transverse aortic diameter >40 mm
19. Patients with anatomic irregularities of the aortic arch or innominate artery that could prevent positioning and stability of the device
20. Patients with contraindication to cerebral MRI
21. Patients who have a planned treatment with any other investigational device or procedure during the study period
22. Patients planned to undergo any other cardiac surgical or interventional procedure (e.g., concurrent coronary revascularization) during the TAVI procedure or within two (2) weeks prior to the TAVI procedure or after the (optional) baseline DW MRI

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2014
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	TriGuard□-HDH Embolic Deflection Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-08-2014
Application type:	First submission
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	NL48386.041.14