A prospective, single arm feasibility pilot study to evaluate the safety and performance of the TriGuard*-HDH Embolic Deflection Device in patients undergoing Transcatheter Aortic Valve Replacement (TAVR)

Published: 13-12-2013
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To demonstrate the safety and performance of the Embolic Deflection Device (TriGuard*HDH) in patients undergoing Transcatheter Aortic Valve Replacement (TAVI).

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

Summary

ID

NL-OMON40150

Source
ToetsingOnline

Brief title
DEFLECT II

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 primary endpoints of this trial are device performance and hierarchical composite device/investigational procedure-related safety during and immediately post TAVI procedure. Both endpoints will be evaluated in the Intention to Treat (ITT) and PP (Per Protocol) population using descriptive statistics. No formal hypothesis testing will be performed.

Secondary outcome

The secondary endpoint analysis of the number and volume of new cerebral lesions by diffusion-weighted MRI at 4+2 days (range 2-6 days) will be evaluated in the PP population.

Study description

Background summary

Embolic stroke during TAVI procedures occurs in approximately 5% off all procedures. Besides this there is also a high number of silent cerebral lesions detected by DW-MRI (up to 80%) which could lead to cognitive decline of the patients later in time. The aim is to reduce both acute stroke but also number of silent lesions in order to avoid invalidation and early onset dementia.

Study objective

To demonstrate the safety and performance of the Embolic Deflection Device

(TriGuard*HDH) in patients undergoing Transcatheter Aortic Valve Replacement (TAVI).

Study design

Prospective, single center, single arm pilot study enrolling up to 15 patients at a single investigational site in the Netherland. Patients meeting eligibility criteria for TAVI and none of the exclusion criteria will be enrolled to receive the Embolic Deflection Device throughout the duration of the TAVI procedure.

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 must be >= 18 years of age.
2. The patient meets indications for TAVI procedure.
3. The patient is willing to comply with specified follow-up evaluations.

Exclusion criteria

1. Patients undergoing TAVI via the trans-axillary, subclavian, or direct aortic route
2. 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.
3. 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 and CK and CK-MB have not returned to normal limits at the time of procedure.
4. Patients who are currently experiencing clinical symptoms consistent with new onset AMI, such as nitrate-unresponsive prolonged chest pain.
5. Patients with impaired renal function (estimated Glomerular Filtration Rate [eGFR] <30, calculated from serum creatinine by the Cockcroft-Gault formula).
6. Patients with torturous/unsuitable anatomy as related to major cerebral arteries in the aortic arch that may interfere with device deployment or remain deployed.
7. Patients with a platelet count <100.000 cells/mm³ or >700.000 cells/mm³ or a WBC <3000 cells/mm³ within 7 days prior to index procedure.
8. Patients with a history of bleeding diathesis or coagulopathy or patients in whom anti-platelet and/or anticoagulant therapy is contraindicated, or will refuse transfusion.
9. Patients who have received any organ transplant or are on a waiting list for any organ transplant.
10. Poor anticipetid fluoroscopic visualization due to obesity or other medical reason

11. Hypotension requiring iv/ia medication or other therapy such as resuscitation and defibrillation
12. Patients with known other medical illness or known history of substance abusethat may cause non-compliance with the protocol, confound the data interpretation or is associated with a life expectancy of less than one year.
13. Patients with a known hypersensitivity or contraindication to aspirin, heparin/bivalirudin, clopidogrel/ticlopidine, nitinol, stainless steel alloy, latex, and/or contrast sensitivity that

cannot be adequately pre-medicated.
14. Patients with a history of a stroke or transient ischemic attack (TIA) within the prior 6 months.
15. Patients with an active peptic ulcer or upper gastrointestinal (GI) bleeding within the prior 6 months.
16. Patients presenting with cardiogenic shock.
17. Patients with severe peripheral arterial disease that precludes the delivery sheath vascular access.
18. Patients with severe calcification/atheroma, friable or mobile atherosclerotic plaque in the aortic arch
19. Patients with contraindication to cerebral MRI.
20. Patients who have a planned treatment with any other investigational device or procedure during the study period.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2014
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:	13-12-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-07-2014
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	NL45294.041.13