TriGUARD 3 TransCranial Doppler (TCD) Ultrasound Study: A prospective, randomized, real-time evaluation of blood filtration with the TriGUARD 3 Embolic Protection Device Using TCD During Transcatheter Aortic Valve Implantation (TAVI).

Published: 24-03-2020
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To demonstrate that the Cerebral Embolic Protection Device (TriGUARD*3) in patients undergoing Transcatheter Aortic Valve Implantation (TAVI) leads to less brain injury as assessed by transcranial Doppler measurements.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON49111

Source
ToetsingOnline

Brief title
Triguard 3 - TCD study

Condition

- Cardiac valve disorders

Synonym
paralysis, Stroke

Research involving
Human

Sponsors and support

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

Intervention

Keyword: embolic protection device, stroke, TAVI

Outcome measures

Primary outcome

Primary endpoint:

* High-intensity transient signals detected by transcranial Doppler (TCD),

during the procedure.

Secondary outcome

Secondary Performance Endpoints:

* Successful device deployment, defined as ability to access the aortic arch

with the TriGUARD* 3 delivery catheter and deploy the device from the

delivery catheter into the aortic arch.

* Successful Device positioning, defined as ability to position the

TriGUARD* 3 device in the aortic arch to cover all major cerebral arteries

* Successful device retrieval, defined as ability to retrieve the TriGUARD* 3

device and remove the intact delivery system

* Device success, defined as successful device deployment, successful device positioning, complete 3-vessel coverage throughout the procedure, and successful device retrieval.

Secondary Safety Endpoints

* Cardiovascular mortality

* Ischemic stroke

o Disabling

o Non-disabling

* Life threatening (or disabling) bleeding

* Acute kidney injury (Stage 3)

* Major vascular complications (excluding TAVI access site-related complications)

Mortality:

* All-cause mortality

o Cardiovascular mortality

o Non-cardiovascular mortality

Stroke (VARC-2 defined), sub-classified as ischemic and hemorrhagic

* All stroke

* Transient ischemic attack (TIA)

Bleeding Complications:

* Life-threatening bleeding (VARC-2)

* Major bleeding related to TriGUARD 3

Acute Kidney Injury (AKI Classification):

Vascular Complications:

* Major vascular complications related to TriGUARD 3

* Major vascular complications related to TAVI

Study description

Background summary

The high incidence of strokes, new embolic lesions and the increased neurologic deficits associated with TAVI indicated a need for improved prevention from any brain damage. Addressing these neurological complications is necessary to optimize outcomes and fully realize the potential of TAVI to treat patients with severe and potentially intermediate and moderate Aortic Stenosis.

Prior designs of Keystone TriGuard cerebral embolic protection devices have shown significant clinical benefits especially in patients with full coverage of all three cerebral branches. The TriGUARD* 3 device is a technological advancement of the TriGuard cerebral embolic protection family. The performance of the TriGUARD* 3 should be improved through better coverage of all three cerebral branches in the majority of TAVI patients by increasing the surface area of the frame and allowing it to conform to the anatomy. The deployment and positioning of the TriGUARD* 3 is now anatomy independent due to the elimination of the lower and upper stabilizers. In addition, by eliminating the upper and lower stabilizers and designing it to self-position, the TriGUARD* 3

should have improved safety since it will be able to position with minimal manipulation, reduce/eliminate interaction with calcification in the innominate artery, and deploy consistently in the desired location. The current study is designed to assess the proof of concept of the next generation TriGUARD* 3 device.

TriGUARD* 3 embolic protection device is a new generation device that is designed to be an improvement in ease of use and extent of coverage over the current CE-mark TriGuard* HDH. The TriGuard HDH device and the TriGUARD* 3 device share the same basic principles of operation and intended use and are manufactured under the same Quality System. Design changes between the TriGuard HDH and TriGUARD* 3 are expected to improve device safety, effectiveness, performance, and ease of use.

Study objective

To demonstrate that the Cerebral Embolic Protection Device (TriGUARD*3) in patients undergoing Transcatheter Aortic Valve Implantation (TAVI) leads to less brain injury as assessed by transcranial Doppler measurements.

Study design

Prospective, single center, randomized study enrolling up to 30 patients at a single investigational site in the Netherlands. Patients meeting eligibility criteria for TAVI and none of the exclusion criteria will be enrolled to receive either the Embolic Protection Device throughout the duration of the TAVI procedure or the standard care (1:1 randomization).

Intervention

Standard of care TAVI procedure, during the procedure the Triguard 3 protection device will be placed.

Study burden and risks

The potential foreseeable risks and discomforts that may be specifically associated with the study device or procedure and any known or expected occurrence rate are explained below. There may be other risks that are not yet known.
* Allergic reaction to nitinol
* Dissection of the innominate artery by improper manipulations, disruption or migration of the TriGUARD 3 device due to passage of other instrumentation, e.g.: balloon, valve, catheter, wire.
* Blue toe syndrome or blue discoloration of a toe
* Femoral bleeding at the access site

* Local trauma to the aortic wall due to the TriGUARD 3 migration
* Livedo reticularis of a mottled skin pattern or a lace-like purplish discoloration of the lower extremities

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 has been informed of the nature of the study, agrees to its provisions and has been provided written informed consent, approved by the appropriate Medical Ethics Committee (EC)
4. The patient is willing to comply with specified follow-up evaluations.

Exclusion criteria

1.Patients undergoing TAVI via the trans-axillary, transapical, subclavian, or direct aortic route
2 Patients with impaired renal function (estimated Glomerular Filtration Rate [eGFR] <30, calculated from serum creatinine by the Cockcroft-Gault formula).
3.Patients with a history of a stroke or transient ischemic attack (TIA) within the prior 6 months.
4.Patients with severe peripheral arterial disease that precludes the delivery sheath vascular access.
5.Patients who have a planned treatment with any other investigational device or procedure during the study period.
6.Patients planned to undergo any other cardiac surgical or interventional procedure during the TAVI procedure (e.g., concurrent coronary revascularization or within 10 days prior to the TAVI procedure. NOTE: Diagnostic cardiac catheterization is permitted within 10 days prior to the TAVI procedure.
7 Patients who have closed temporal window(s).
8. Patients with scheduled valve-in-valve procedure

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	TriGuard 3: embolic protection device
Registration:	No

Ethics review

Approved WMO Date:	24-03-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL70891.100.19