Antiplatelet therapy for patients undergoing transcatheter aortic valve implantation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25546

Source
NTR

Brief title
POPular TAVI

Health condition

Aortic valve disease; aortic valve stenosis; bleeding; stroke; thrombosis; platelet inhibitors.

Sponsors and support

Primary sponsor: St Antonius Hospital, Nieuwegein, the Netherlands
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

The primary outcome is a safety endpoint, defined as freedom of all bleeding complications at 1 year after TAVI. The co-primary outcome is the safety endpoint defined as freedom of

non-procedure related bleeding complications at 1 year after TAVI. For the classification of bleeding complications the Bleeding Academic Research Consortium Definition for Bleeding (BARC) bleeding classification is primarily used according to the Valve Academic Research Consortium (VARC).

Secondary outcome

The secondary outcome is a net-clinical benefit endpoint, defined as freedom of the non-hierarchical composite of cardiovascular mortality, non-procedure related bleeding, stroke, or myocardial infarction at 1 year after TAVI.

The co-secondary outcome is an efficacy endpoint, defined as freedom of the non-hierarchical composite of cardiovascular mortality, ischemic stroke, or myocardial infarction at 1 year after TAVI.

Study description

Study objective

Monotherapy with aspirin or oral anticoagulation after TAVI is safer than the addition of clopidogrel for 3 months, without being less clinically beneficial.

Study design

30 days, 3 months, 6 months, and 12 months after TAVI.

Intervention

Cohort A
Random 1:1 allocation to aspirin alone (at least until 1 year) (intervention) versus clopidogrel (3 months) + aspirin (at least until 1 year) (control), 1 day before TAVI in patients without an indication for OAC at baseline;

Cohort B
Random 1:1 allocation to OAC alone (intervention) versus OAC + clopidogrel (3 months) (control), 1 day before TAVI in patients with an indication for OAC at baseline.

Contacts

Public
Koekoekslaan 1, 3435CM Nieuwegein

J.M. ten Berg
[default]
The Netherlands
+31 88 320 1121
Scientific
Koekoekslaan 1, 3435CM Nieuwegein
J.M. ten Berg
[default]
The Netherlands
+31 88 320 1121

Eligibility criteria

Inclusion criteria

Cohort A
1. Patient has provided written informed consent.

Cohort B
2. Need for long-term oral anticoagulation;
3. Patient has provided written informed consent.

Exclusion criteria

Cohort A
1. Need for long-term oral anticoagulation;
2. Drug-eluting stent implantation within 3 months prior to TAVI procedure;
3. Bare-metal stent implantation within 1 month prior to TAVI procedure;
4. Allergy or intolerance to aspirin or clopidogrel.

Cohort B
1. Drug-eluting stent implantation within 3 months prior to TAVI procedure;
2. Bare-metal stent implantation within 1 month prior to TAVI procedure;
3. Use of non-vitamin K oral anticoagulation (NOAC);
4. Allergy or intolerance to OAC or clopidogrel.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2014
Enrollment:	1000
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-11-2014
Application type:	First submission

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
NTR-new	NL4796

Register	ID
NTR-old	NTR4936
Other	: NCT02247128

Study results