Periprocedural continuation versus interruption of oral anticoagulant drugs during transcatheter aortic valve implantation

No registrations found.

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

Summary

ID

NL-OMON26988

Source
Nationaal Trial Register

Brief title
POPular PAUSE TAVI trial

Health condition

Aortic Valve Stenosis

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

A composite of cardiovascular mortality, stroke, myocardial infarction, major vascular complications and major, disabling and life-threatening bleeding complications at 30 days post TAVI as defined by the Valve Academic Research Consortium(VARC)-2 criteria.

Secondary outcome

1. Thromboembolic complications at 30 days: composite of stroke, transient ischemic attack, systemic embolism, distal embolization, myocardial infarction, and cardiovascular death not caused by bleeding
2. Bleeding and vascular access site complications: composite of bleeding and vascular access site and access-related complications (except distal embolization and systemic embolism)
3. Early safety as defined by VARC-2 criteria at 30 days: composite of all-cause mortality, all stroke, life-threatening bleeding, stage 2 or 3 acute kidney injury, coronary artery obstruction requiring intervention, major vascular complication, and valve-related dysfunction requiring repeat procedure (balloon valvuloplasty or valve replacement)
4. Clinical efficacy as defined by VARC-2 criteria at 30 days: composite of all-cause mortality, all stroke, hospitalizations for valve related symptoms or worsening congestive heart failure, New York Heart Association class for heart failure 3/4, and valve-related dysfunction (mean aortic valve gradient >=20 mmHg, effective orifice area (EOA) <=0.9-1.1 cm^2 and/or Doppler velocity index (DVI) <0.35 m/s, AND/OR moderate or severe prosthetic valve regurgitation)
5. All-cause death at 30 days.
6. Quality of life assessed by Short Form-12 Questionnaire at 3 months
7. Quality of life assessed by Toronto Aortic Stenosis Questionnaire at 3 months
8. Quality of life assessed by Kansas City Cardiomyopathy Questionnaire at 3 months
9. Stroke at 3 months
10. Stroke and transient ischemic attack at 3 months

Study description

Background summary

Transcatheter aortic valve implantation (TAVI) is a rapidly growing treatment option for patients with aortic valve stenosis. Stroke is a feared complication of TAVI, with an incidence of around 4-5% in the first 30 days. Up to 50% of patients undergoing TAVI have an indication for oral anticoagulants (OAC) mostly for atrial fibrillation. OAC use during TAVI could increase bleeding complications, but interruption during TAVI may increase the risk for thromboembolic events (i.e. stroke, systemic embolism, myocardial infarction). Recent observational data suggest that periprocedural continuation of OAC is safe and might decrease the risk of stroke. Beside the potential reduction of thromboembolic events, continuation of OAC is associated with an evident clinical ancillary benefit for patients and staff. Since periprocedural OAC interruption not infrequently leads to misunderstanding and potentially dangerous situations, when patients are not properly informed before hospital

admission or may experience difficulties with the interruption regimen.

Study objective

Periprocedural continuation of oral anticoagulants is safe and might decrease thromboembolic complications without an increase in bleeding complications at 30 days.

Study design

Hospital discharge, 30 days, 3 months

Intervention

Uninterrupted periprocedrual oral anticoagulant treatment

Contacts

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Eligibility criteria

Inclusion criteria

- Planned transfemoral transcatheter aortic valve implantation procedure
- Established indication for oral anticoagulation
- Written informed consent

Exclusion criteria

Patients at high risk for thromboembolism for who interruption of oral anticoagulants is no

option:
- Mechanical heart valve prosthesis
- Intracardiac thrombus
< 3 months after venous thromboembolism
< 6 months after transient ischemic attack or stroke in patients with atrial fibrillation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-11-2020
Enrollment:	858
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-11-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56111
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9066
CCMO	NL73805.100.20
OMON	NL-OMON56111

Study results