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

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To evaluate the efficacy and safety of peri-procedurally continued versus interrupted oral anticoagulants in patients undergoing transcatheter aortic valve implantation.

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

Summary

ID

NL-OMON56111

Source
ToetsingOnline

Brief title
POPular PAUSE TAVI trial

Condition

- Cardiac valve disorders

Synonym
TAVI, transcatheter aortic valve implantation

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: ZonMW,St. Antonius Onderzoeksfonds

Intervention

Keyword: Oral Anticoagulants (OAC), Stroke (CVA), Transcatheter aortic valve implantantion (TAVI), Transcatheter aortic valve replacement (TAVR)

Outcome measures

Primary outcome

A composite of cardiovascular mortality, all stroke, myocardial infarction,

major vascular complications and type 2-4 bleeding complications at 30 days

post TAVI as defined by the VARC-3 criteria.

Secondary outcome

Secondary endpoints:

- Procedure related primary endpoints at 30 days.

- Procedure related bleeding complications (type 1-4 bleeding) at 30 days as

defined by the VARC-3 criteria.

- Procedure related thromboembolic complications (all stroke (except

haemorrhagic), TIA, myocardial infarction, systemic embolism (vascular

complications: distal embolization (non-cerebral) from a vascular source)) at

30 days as defined by the VARC-3 criteria.

- Thromboembolic complications (all stroke (except haemorrhagic), TIA,

myocardial infarction and systemic embolism (vascular complications: distal

embolization (non-cerebral) from a vascular source)) at discharge and 30 days

as defined by the VARC-3 criteria.

- Neurologic events (overt CNS injury, covert CNS injury, neurologic

dysfunction (acutely symptomatic) without CNS injury) at discharge and 30 days

as defined by the VARC-3 criteria.

- Cerebrovascular events (all stroke, TIA) at discharge and 30 days as defined by the VARC-3 criteria.

- All stroke at discharge and 30 days as defined by the VARC-3 criteria.

- Bleeding complications (type 1-4 bleeding) at discharge and 30 days as defined by the VARC-3 criteria.

- Early safety at 30 days as defined by VARC-3 criteria, freedom from:

- All-cause mortality

- All stroke

- VARC type 2-4 bleeding

- Major vascular, access-related, or cardiac structural complication

- Acute kidney injury stage 3 or 4

- Moderate or severe aortic regurgitation

- New permanent pacemaker due to procedure related conduction abnormalities

- Surgery or intervention related to the device

- Clinical efficacy at 30 days as defined by VARC-3 criteria, freedom from:

- All-cause mortality

- All stroke

- Hospitalization for procedure- or valve-related causes

- KCCQ Overall Summary Score <45 or decline from baseline of >10 point

- All-cause death at discharge and 30 days.

- Cardiovascular death at discharge and 30 days.

- Quality of life (assessed by SF-12, KCCQ, and TASQ) at 30 days and 90 days.

Other endpoints:

- NYHA classification for heart failure.

- Rehospitalisation.

- Permanent pacemaker implantation.

- Cost-effectiveness.

- Separate and combined components (e.g. thromboembolic, neurologic, vascular and bleeding complications) of primary and secondary endpoints, both at 30 days and hospital discharge.

- Bleeding as classified by and BARC at 30 days and hospital discharge.

- Other composite endpoints as proposed by VARC-3 definitions and its separate components.

Study description

Background summary

Transcatheter aortic valve implantation (TAVI) is a rapidly growing treatment option for patients with aortic valve stenosis. Nowadays, also patients with low risk undergo TAVI. Stroke is a feared and frequently occurring 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; vitamin-k-antagonist or NOAC) 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 shows a lower risk of stroke in patients continuing OAC during TAVI compared to in patients interrupting OAC, without an increase in bleeding. We hypothesize that periprocedural continuation of OAC is safe and might decrease thromboembolic complications without an increase in bleeding complications at 30 days.

Study objective

To evaluate the efficacy and safety of peri-procedurally continued versus interrupted oral anticoagulants in patients undergoing transcatheter aortic valve implantation.

Study design

Randomised controlled open-label multicentre trial

Intervention

Continuation versus interruption of OAC during TAVI

Study burden and risks

At this moment no clear evidence or guidance exists regarding continuation or interruption of oral anticoagulants during TAVI. There is a variety in clinical practise. Some hospitals advise their patients to interrupt OAC up to 7 days before and after TAVI, with or without bridging, some advise their patients to continue OAC. So we do not know what is best for the patient, and what advantage the patient might have from one of the two strategies. The burden for the patient will be limited to an instruction regarding periprocedural OAC use, and questionnaires at baseline, after 30 days and after 3 months.

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

• Planned transfemoral or transsubclavian TAVI procedure
• Uses oral anticoagulation at screening
• Provided written informed consent

Exclusion criteria

Patients at high risk for thromboembolism for who interruption of oral anticoagulants is no option, i.e.:
- Mechanical heart valve
- Intracardiac thrombus
- < 3 months after venous thromboembolism
- < 6 months after TIA/stroke in patients with atrial fibrillation

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Completed

Start date (anticipated):	25-11-2020
Enrollment:	778
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-10-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-04-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-05-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-06-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-06-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	05-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-11-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-12-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-06-2022
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Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-01-2023
Application type:	Amendment
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Approved WMO Date:	20-07-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-08-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-11-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	07-12-2023
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

ID: 26988
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2020-001817-20-NL
ClinicalTrials.gov	NCT04437303
CCMO	NL73805.100.20

Study results

Date completed:	22-05-2024
Results posted:	03-10-2024

First publication
31-08-2024