PeRcutaneous cOronary intervention before Transcatheter Aortic Valve Implantation trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON56109

Source
ToetsingOnline

Brief title
PRO TAVI

Condition

- Coronary artery disorders

Synonym
Coronary artery disease / Aortic valve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Coronary artery disease, Cost-effectiveness, Percutaneous coronary intervention (PCI), Transcatheter aortic valve implantation (TAVI)

Outcome measures

Primary outcome

The primary outcome will be a composite endpoint consisting of all-cause mortality, myocardial infarction, stroke and major bleeding (VARC-3 type 2 - 4) during one-year follow-up.

Secondary outcome

Secondary endpoints are a composite of all-cause mortality, stroke and myocardial infarction, (1) individual components of primary endpoint, (2) All VARC-3 bleeding and BARC bleeding (BARC > 1), (3) rehospitalization (4) any revascularization, (5) anginal status (Seattle questionnaire), (6) Canadian Cardiovascular Society (CCS) and New York Heart Association (NYHA) class, (7) quality of life (QoL), and (8) cost effectiveness, (9) acute kidney injury (stage 3 and 4), (10) study lesion revascularization, and (11) study vessel revascularization at 4 and 12 months after randomization. Furthermore, (12) left ventricular function one year after randomization will be compared to baseline.

Study description

Background summary

Coexisting coronary artery disease (CAD) is highly prevalent in patients undergoing transcatheter aortic valve implantation (TAVI) because of a severe aortic valve stenosis (AoS). Several studies did not find a correlation between

severity of CAD and revascularization with post-TAVI clinical outcome. Even more, a recent meta-analysis showed that percutaneous coronary intervention (PCI) before TAVI in patients with a severe AoS and concomitant CAD did not lead to an additional clinical advantage. However, the available literature is predominantly based on single-center studies of relatively small sample size, and represents the early experience with TAVI. More importantly, most cardiologists believe that these data are based on treatment bias and therefore, current practice is still to perform PCI of major coronary arteries. We hypothesize that performing a TAVI without PCI of the coexisting CAD before TAVI is not inferior to performing TAVI with preceding PCI.

Study objective

Aim of the proposed project will be to evaluate in a large and prospective randomized way the safety and cost-effectiveness of performing TAVI without full revascularization of major coronary arteries before the valve replacement.

Study design

The proposed trial is an investigator-initiated, multicenter, randomized, open-label, non-inferiority trial.

Intervention

The TAVI procedure will be performed according to standard clinical practice. Implantation technique, choice of the valve type and size are at the operator's discretion depending on clinical and anatomical considerations. All patients will undergo diagnostic coronary angiography before TAVI to screen for the presence of significant coronary artery disease as a standard of care. Patients will be randomized to undergo TAVI with (usual care) or without (intervention group) preceding standard PCI of the present coronary artery disease.

Study burden and risks

The work-up and TAVI procedure itself will be performed according to standard clinical practice. Patients will have a work-up as a standard of care including coronary angiography in the referral hospital, echocardiogram and computed tomography (CT) scan. Omitting PCI in the intervention group would prevent patients from undergoing unnecessary extra procedure(s). Thereby, potential periprocedural and late complications in this fragile patient population of the PCI procedure (e.g., vascular perforation, early or late stent restenosis or thrombosis) are prevented. Additionally, PCI necessitates the use of dual antiplatelet therapy and therefore increases the risk for (periprocedural) bleeding during TAVI. However, theoretically, periprocedural complications of the TAVI procedure (e.g., ischemia due to rapid pacing and balloon inflation) could increase if optimal revascularization before the TAVI procedure is

omitted. Furthermore, access to the coronary arteries is more challenging after TAVI. Therefore, the incidence of so-called hard endpoints (mortality, myocardial infarction, stroke, major bleeding) or secondary endpoints like persistence of anginal complaints or the need for interventions during the first year after randomization will be closely monitored.

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

- Patients schedueled for TAVI; AND
- Concomitant coronary artery disease.

Exclusion criteria

- an unprotected left main stenosis (no patent bypass graft on the LAD or RCx) > 50% or left main equivalent;
- Significant native coronary artery disease, but patent bypass surgery stents;
- Contraindication for DAPT;
- Patient with life expectancy < 1 year

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:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-10-2021
Enrollment:	466
Type:	Actual

Ethics review

Approved WMO Date:	10-09-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	24-01-2022

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-05-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-08-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-11-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-01-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-07-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-01-2025
Application type:	Amendment
Review commission:	METC NedMec

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: 20879
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77915.041.21