TransCatheter Aortic Valve Implantation and Fractional Flow Reserve-Guided Percutaneous Coronary Intervention versus Conventional Surgical Aortic Valve Replacement and Coronary By-Pass Grafts for Treatment of Patients with Coronary MultiVessel Disease and Aortic Valve Stenosis

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To investigate whether FFR-guided PCI and TAVI strategy for treatment of MVD and AS will be non-inferior to CABG and SAVR for a composite primary endpoint of all-cause mortality, stroke, myocardial infarction, coronary or valve re-intervention and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50705

Source
ToetsingOnline

Brief title
TCW

Condition

- Other condition
- Cardiac valve disorders

Synonym
multivessel disease and aortic valve stenosis

Health condition

meervatslijden

Research involving
Human

Sponsors and support

Primary sponsor: Maatschap Cardiologie Zwolle
Source(s) of monetary or material Support: Industrie,Medtronic

Intervention

Keyword: CABG, FFR-guided PCI, SAVR, TAVI

Outcome measures

Primary outcome

The primary endpoint is a composite of all-cause mortality, myocardial infarction, disabling stroke, unscheduled clinically-driven target vessel revascularization, valve re-intervention, and life threatening or disabling bleeding at one year

Secondary outcome

- MACE (a composite of cardiovascular mortality, all stroke, myocardial infarction, unscheduled coronary or valve re-intervention) at one year
- All-cause mortality and all stroke at 30 days and at one year

Study description

Background summary

Patients with multivessel coronary disease (MVD) frequently have concomitant

moderate or severe Aortic Stenosis (AS). The current guidelines indicate coronary artery by-pass graft (CABG) as the gold standard for treatment of MVD. If moderate to severe or severe AS is present at the time of CABG, surgical aortic valve replacement (SAVR) is performed in the same setting as CABG.
The treatment of MVD has undergone significant evolution in the last decade. In patients with low Syntax score (SS), percutaneous coronary intervention (PCI) is considered as equivalent treatment with CABG and widely performed in the real life. In patients with high risk for CABG such approach is applied also for patients with a high SS.
Fractional Flow Reserve (FFR) is at the present the gold standard technique to detect ischemia and guide revascularization in the cathlab. It is believed that an FFR-guided PCI for MVD might be non-inferior to CABG.
Parallel to SAVR, minimal invasive approaches by use of Transcatheter Aortic Valve Implantation (TAVI) have been introduced and are being widely used especially in older patients and patients with high risk or contraindication for SAVR.
At the present, no trial has focused on patients with concomitant MVD and AS. We therefore propose a prospective randomized controlled multicenter international clinical trial comparing TAVI and staged FFR guided PCI versus conventional CABG and SAVR in a population of patients with MVD and concomitant moderate to severe or severe AS.

Study objective

To investigate whether FFR-guided PCI and TAVI strategy for treatment of MVD and AS will be non-inferior to CABG and SAVR for a composite primary endpoint of all-cause mortality, stroke, myocardial infarction, coronary or valve re-intervention and life-threatening or disabling bleeding at one year.

Study design

The TCW trial is a prospective, randomized, controlled, open label, multicenter, international, non-inferiority trial. Angiography and echocardiography of all patients with MVD and AS will be discussed in the local site Heart Team (HT: composed of at least one cardiac surgeon and one interventional cardiologist with TAVI experience). If patients comply with inclusion and exclusion criteria they will be randomized in a 1:1 fashion between FFR-guided PCI and TAVI (experimental arm) and CABG and SAVR (comparative arm).

Intervention

FFR-guided PCI and TAVI

Study burden and risks

There is no additional risk for patients associated with study participation, besides the risks of the procedures (both treatment arms are standard procedures).

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) Symptomatic patients aged >=70 years with AS fulfilling one of these criteria (AVA <=1 cm2; mean gradient >=40mmHg; Aortic jet velocity >4 m/sec; or Velocity index <= 0.25) feasible for treatment by both trans femoral or subclavian approach TAVI as well as conventional SAVR and where the HT decides that treatment is needed (final decision is left to the HT)
2) Presence of >=2 de novo coronary lesions of >=50% diameter stenosis on visual estimation located in any of main epicardial coronary arteries or side branches

of a lumen caliber of more than 2 mm or single LAD lesion with more than 20 mm length or involving a bifurcation (complex), feasible for treatment with CABG as well as PCI (HT decision)
3) Patients willing and capable to provide written informed consent

Exclusion criteria

1) Patients in cardiogenic shock or acute heart failure, requiring inotropic agents during procedure and/or i.v. diuretics <48 hours before procedure
2) Left ventricular ejection fraction <30%
3) Concomitant presence of other than aortic valve disease requiring intervention
4) Previous CABG, SAVR, TAVI or thoracotomy for any other reason
5) Bicuspid or unicuspid aortic valve
6) Recent myocardial infarction (less than 2 weeks)
7) Involvement of left main trifurcation (all three branches being larger than 2 mm)
8) Expected total stent length more 60mm per vessel
9) FFR measurement judged impossible
10) Life expectancy <1 year
11) Known malignancy
12) Contraindication for dual antiplatelet therapy or expected surgical intervention requiring interruption of Dual Antiplatelet Therapy (DAPT) in the first 6 months
13) Reduced renal function (GFR <29 ml/min/1.73m2; KDOQI stage 4 and 5)
14) Previous disabling stroke, TIA in the last 6 months, or known severe stenosis of carotid or vertebral arteries
15) Participation in other investigational clinical trials

Study design

Design

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):	31-05-2018
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-12-2017
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	06-02-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-02-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	14-05-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-05-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Approved WMO Date:	18-06-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	18-06-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	21-05-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-05-2019
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	06-02-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-02-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NL62994.075.17