Dlagnostic and prognostic value of intracoronary physiologic indices and need for revascularisation in severe aortic VAlve disease (DIVA)

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29366

Source
NTR

Brief title
DIVA

Health condition

Severe aortic valve stenosis
Coronary artery disease

Sponsors and support

Primary sponsor: Academical medical centre (AMC, Amsterdam)
Source(s) of monetary or material Support: Academical medical centre (AMC, Amsterdam)

Intervention

Outcome measures

Primary outcome

- MACE (A composite of all cause death, documented MI and any revascularisation (urgent/non-urgent).

Secondary outcome

- Overall MACE (cost and cost effectiveness, functional class, number of anti-anginal medication, rate of non-urgent revascularization, and rate of cerebrovascular event),

- Standard follow-up criteria (physical examination, ECG, standard laboratory tests)

- Valve function and left ventricular function parameters (as measured with cardiac ultrasonography),

- Cardiac symptoms (dyspnoea (New York Heart Association/ NYHA classification),

- angina pectoris (Canadian Cardiologist Society/ CCS score),

- quality of life (QoL).

Study description

Background summary

Aortic stenosis (AS) is a disease which predominantly prevails in the elderly population, often accompanied by (stable) coronary artery disease (CAD). Established intracoronary flow- and pressure measurements (FFR, CFR, MR) to assess coronary hemodynamic and the severity of - and need for revascularisation of atherosclerotic coronary lesions are not yet fully understood (and not validated) for use in patients with concomitant diseases. Furthermore, there is no definite data on whether or not to treat CAD in patients who will undergo TAVI regarding symptoms and prognostic value.

This RCT (2x105 pts) will investigate diagnostic and prognostic value of FFR in patients who undergo TAVI for their severe aortic valve stenosis. It will make clear the symptomatic and prognostic value of revascularisation in patients with AS and concommitant CAD.

Study objective

- FFR is a valid measurement to determine hemodynamic severity of coronary stenoses in patients with severe aortic stenosis

- FFR-guided PCI with concommitant TAVI reduces MACE and revascularisations

Study design

+6-8 weeks after TAVI-procedure

+12 months after TAVI procedure

Intervention

FFR-guided PCI after TAVI; re-catheterisation 2 months after TAVI-procedure

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with severe (senile) aortic stenosis (AVA <1,0cm, mean gradient >40mm and maximum jet velocity >4 m/s or or aortic valve area index ¡Ü0.6 cm2/m2.)

- Patients are non-eligible for conventional surgical aortic valve replacement due to age, medical history or co-morbidity and thus eligible for T(F)-AVI as decided by the heart-team.

- Patient has coronary artery disease as depicted on screening CAG (defined as ¡Ý1 coronary stenosis >50%)

- Patient understands the study requirements and the treatment procedures, and provides written informed consent.

- Patient agrees and is capable of returning to the study hospital for all required scheduled follow up visits

Exclusion criteria

- Patient is able to give informed consent

- Absence of coronary artery disease (defined as ¡Ý1 coronary stenosis >50% as depicted on coronary arteriogram during TAVI-screening)

- Subjects with an acute STEMI within 30 days preceding the index procedure (TAVI).

- Inability to get per procedural reliable, intracoronary measurements (due to place of lesion, unreliable signals, mechanical defects etc.)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	210
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL6328
NTR-old	NTR6520
Other	METC : 2017_005

Study results