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

Gepubliceerd: 10-11-2016 Laatst bijgewerkt: 18-08-2022

- 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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29366

Bron
NTR

Verkorte titel
DIVA

Aandoening

Severe aortic valve stenosis
Coronary artery disease

Ondersteuning

Primaire sponsor: Academical medical centre (AMC, Amsterdam)
Overige ondersteuning: Academical medical centre (AMC, Amsterdam)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

- 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

Onderzoeksopzet

+6-8 weeks after TAVI-procedure

+12 months after TAVI procedure

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	210
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6328
NTR-old	NTR6520
Ander register	METC : 2017_005

Resultaten