Cardiac output, cerebral perfusion and cognition in patients with severe aortic valve stenosis undergoing transcatheter aortic valve implantation

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21148

Bron
NTR

Verkorte titel
CAPITA

Aandoening

aortic valve stenosis

Ondersteuning

Primaire sponsor: This study is supported by grants from the Dutch Heart Foundation (CVON Heart Brain Connection 2012-06 & 2018-28), Dutch Federation of University Medical Centres, the Netherlands Organisation for Health Research and Development and the Royal Nederlands Academy of Sciences.
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Cardiac output (L/min), cerebral blood flow (mL/100g/min, change in %, relative to baseline) and cognitive functioning (extensive testing).

Toelichting onderzoek

Achtergrond van het onderzoek

Cognitive impairment is common (21-39%) among patients with severe aortic valve stenosis. The proof-of-concept CP-TAVI study showed increased cardiac output following transcatheter aortic valve implantation (TAVI) was associated with increased cerebral blood flow. We hypothesize increased cerebral blood flow (CBF) subsequently leads to improved cognitive functioning. Additionally, silent micro emboli caused by crushing of the calcified native valve during TAVI may cause cognitive deterioration. If it could be predicted which patients are at risk for TAVI induced cerebral micro emboli, these patients could benefit from cerebral protection devices, preventing cognitive decline. Therefore we assess 1A) whether an increase in cardiac output after TAVI is associated with an increase of global CBF; 1B) regional differences in CBF after TAVI; 1C) whether (global or regional) increased CBF is associated with improved cognitive functioning; 1D) patient and procedural characteristics associated with increased cardiac output, CBF and cognitive functioning; 2A) the incidence and volume of new white matter hyperintensities (WMH) after TAVI; 2B) patient and procedural predictors for the increase in WMH volume, including baseline aortic valve calcification volume, measured with computed tomography; 2C) if aortic valve calcification volume predicts new white matter hyperintensities, define a cut-off value for high-risk patients; 2D) assess whether the increase in white matter hyperintensity volume is associated with deterioration of cognitive scores. In a prospective observational cohort of 142 patients undergoing TAVI, we measure cardiac output using inert gas rebreathing; cerebral blood flow using arterial spin labelling MRI; and cognitive functioning using a neuropsychological test battery, prior to TAVI (<24 hours) and at 3 months follow-up.

Doel van het onderzoek

After TAVI, cardiac output will increase, which leads to increased cerebral blood flow (CBF) and subsequently to improved cognitive functioning. If it could be predicted which patients are at risk for TAVI induced cerebral micro emboli, these patients could benefit from cerebral protection devices, preventing cognitive decline.

Onderzoeksopzet

Baseline (<24 hours before TAVI) and follow-up 3 months after TAVI

Onderzoeksproduct en/of interventie

Transcatheter aortic valve implantation (TAVI)

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Astrid van Nieuwkerk

020 566603

Wetenschappelijk

Amsterdam UMC, location AMC
Astrid van Nieuwkerk

020 566603

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Severe aortic valve stenosis (aortic valve area <1cm2 and/or mean aortic valve gradient exceeds 50 mmHg) of a native valve; able and willing to give informed consent; eligible for transfemoral TAVI, age > 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Presence of MRI contra-indication; inability to lay flat for 30 minutes; weight > 130 kg; neurological presence; active malignant disease; insufficient mastery of the Dutch language; alcohol use inability to withdraw 24 hours; non-atherosclerotic vascular disease (eg vasculitis).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	142
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-06-2020
Soort:	Eerste indiening

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	NL8721
Ander register	METC AMC : METC 2019_08, NL72247.018.19

Resultaten