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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52941

Source
ToetsingOnline

Brief title
CAPITA

Condition

- Cardiac valve disorders

Synonym
aortic valve stenosis, cerebral pefusion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,KNAW;ZonMW,Nederlandse Hartstichting

Intervention

Keyword: aortic valve replacement, aortic valve stenosis, cerebral perfusion, TAVR

Outcome measures

Primary outcome

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

Secondary outcome

Regional differences in changes in CBF after TAVI (Δ ml/min/m3); Identify patient and procedural characteristics associated with increased cardiac output, CBF, white matter hyperintensity volume and cognitive functioning ; incidence and volume of new white matter hyperintensities after TAVI (number and volume mm3, relative increase %); aortic valve calcification volume (mm3), measured with computed tomography

Study description

Background summary

Cardiovascular disease and cognitive diseases are closely related. 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.

Study objective

the objectives of the CP-TAVI II study are 1A) to identify whether an increase in cardiac output after TAVI is associated with an increase of global CBF; 1B) explore regional differences in CBF after TAVI; 1C) determine whether (global or regional) increased CBF is associated with improved cognitive functioning; 1D) identify patient and procedural characteristics associated with increased cardiac output, CBF and cognitive functioning; 2A) identify the incidence and volume of new white matter hyperintensities after (WMH) TAVI; 2B) evaluate 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.

Study design

Prospective observational study, measuring cardiac output (routine echocardiography), cerebral blood flow (arterial spin labelling magnetic resonance imaging) and cognitive functioning (neuropsychologist) prior to TAVI (<24 hours) and at 3 month follow-up

Study burden and risks

In addition to usual treatment, patients will undergo an MRI scan (30 minutes), and multiple cognitive tests (90 minutes). The first set of these three tests will be done during standard admission 24 hours prior to TAVI and the second set will be done during routine follow-up outpatient appointment. Additional hospital visits are not needed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

• Presence of severe aortic valve stenosis (aortic valve area < 1 cm2 and/or mean aortic valve gradients exceeds 50 mmHg) of a native valve
• Be able and willing of giving informed consent
• Eligible for transfemoral TAVI
• Age >18 years

Exclusion criteria

• Presence of a magnetic resonance imaging (MRI) contra-indication.
• Orthopnea or inability to lay flat for 30 minutes
• Bodyweight >130 kg
• Neurological disease
• Insufficient mastery of the Dutch language
• Alcohol use >3 units per day or inability to withdraw 24 hours.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-08-2020
Enrollment:	152
Type:	Actual

Ethics review

Approved WMO Date:	05-03-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-07-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam

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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	NL72247.018.19