Cerebral perfusion in patients with severe aortic valve stenosis undergoing aortic valve replacement.

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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-OMON44893

Source
ToetsingOnline

Brief title
Cerebral perfusion in patients with severe aortic valve stenosis

Condition

- Cardiac valve disorders

Synonym
blood circulation, Cerebral perfusion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aortic valve replacement, Aortic valve stenosis, Cardiac output, Cerebral perfusion

Outcome measures

Primary outcome

Cerebral perfusion in rest and in response to moderate exercise (handgripping or light cycling) and a visual stimulus in patients with aortic valve stenosis (prior to and after aortic valve replacement) and healthy age-matched controls.

Secondary outcome

* Cerebral perfusion in rest and in response to exercise in patients and healthy controls at both arterial (TCD) and microvascular level (arterial spin labeling MRI).

Study description

Background summary

Cardiovascular disease is associated with loss of cognitive functioning. Both disorders are more common in elderly people. The condition of the heart and the large vessels determines the flow of blood to the brain and we propose a more central role for the heart than previously assumed. According to the traditional paradigm of cerebrovascular autoregulation in humans, the cerebral perfusion (cerebral blood flow; CBF) is predominantly influenced by the cerebral perfusion pressure (CPP). Cerebral autoregulation maintains constant CBF within a wide range of CPP by regulating the cerebrovascular resistance. However, we and others have demonstrated that a decline in perfusion pressure within the cerebral autoregulatory range (e.g. when standing up from a sitting position) may lower CBF. This reduction might be attributed by a change in systemic flow (cardiac output). CBF has been demonstrated to be substantially but reversibly reduced in patients with NYHA class III/IV heart failure, with normalization of CBF following cardiac transplantation [1]. This observation indicates that redistribution of cardiac output inadequately secures cerebral perfusion in patients with severe chronic heart failure. We hypothesize that

subnormal recruitment of cardiac output in patients with aortic stenosis reduces the regional CBF response to small muscle exercise (handgripping or light cycling) and a visual stimulus, and that the subnormal CBF during exercise is (partially) restored following adequate surgical aortic valve replacement (AVR) or transcatheter aorta valve implantation (TAVI).

Study objective

The primary objective is to investigate cerebral perfusion in rest and in response to moderate exercise (handgripping or light cycling) and a visual stimulus in patients with severe aortic valve stenosis prior and after surgical or transcatheter aortic valve replacement.

Study design

Observational. Hemodynamic (e.g. blood pressure, cardiac output and heart rate), cerebral (CBF velocity by transcranial Doppler ultrasonography and whole brain CBF by arterial spin labelling MRI) and respiratory parameters (PetCO2) will be recorded in rest, during a sit-to-stand test and in response to moderate exercise (handgripping or light cycling) and a visual stimulus. This study protocol will be performed prior to and after treatment to investigate the effect of aortic valve replacement (either surgical or by TAVI). Hemodynamic parameters will also be measured (fingercuff; Nexfin) as well as kidney perfusion perfusion (ultrasound) during the procedure to study the direct effect of aortic valve replacement on systemic hemodynamics. Age-matched volunteers will serve as controls and will follow the same study protocol as the patients. Study procedures are performed during admission prior to the aortic valve replacement (2.5 hours), 3 months after the procedure in combination with the clinical follow-up appointment (2.5 hours) and at 1 year follow up (5 minutes).

Study burden and risks

No benefits and risks are anticipated for the subjects in the study population

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

Cohort A (N<=30):
* Age between 50-75 years
* Presence of aortic stenosis (aortic valve area less than 1 cm2)
* Eligible for a surgical aortic valve replacement (AVR)
* Expected aortic valve size of 23-25 mm;Cohort B (N<=30):
Age between 50-95 years
* Presence of aortic stenosis (aortic valve area less than 1 cm2)
* Eligible for transcatheter aorta valve implantation (TAVI)

Exclusion criteria

Cohort A:
* Additional complex surgical procedures indicated (e.g. restoration of aortic root)
* Medical history of neurological disease, active malignant disease/ cardio- toxic treatment and/or venous insufficiency
* Contraindication to MRI exposure (*vragenlijst MRI onderzoek*)
* Smoking or having smoked less than 10 years ago;Cohort B:
* Medical history neurological disease, active malignant disease/ cardio- toxic treatment and/or venous insufficiency
* Contraindication to MRI exposure (*vragenlijst MRI onderzoek*)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2015
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-10-2016
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29396
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50524.018.14
OMON	NL-OMON29396