Cerebral perfusion in patients with severe aortic valve stenosis undergoing transcatheter aortic valve implantation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29396

Source
Nationaal Trial Register

Brief title
CP-TAVI

Health condition

Severe aortic valve stenosis

Sponsors and support

Primary sponsor: This study is supported by grants from the Dutch Heart Foundation (CVON 2012-06 Heart Brain Connection).
Source(s) of monetary or material Support: This study is supported by grants from the Dutch Heart Foundation (CVON 2012-06 Heart Brain Connection).

Intervention

Outcome measures

Primary outcome

Increase of cerebral blood flow (mL blood/100g tissue /min) after TAVI

Secondary outcome

Incidence and volume of new white matter hyperintensities

Study description

Background summary

Despite the striking load of peri-procedural cerebral micro embolizations, cognitive functioning improves after transcatheter aortic valve replacement (TAVI). We hypothesize that the decreased cardiac output in patients with severe aortic valve stenosis leads to reduced cerebral blood flow which may be restored by TAVI. The objective of the current trial is to examine whether cerebral blood flow improves after TAVI. Moreover, predictors for an increase in cerebral blood flow will be evaluated. Fifty patients with severe aortic valve stenosis will undergo TAVI and prospective assessment of cerebral blood flow using arterial spin label magnetic resonance imaging (ASL-MRI) at baseline and 3 month follow-up. Moreover, the incidence of new white matter hyperintentsities will be evaluated. Finally, in a sub cohort, cerebral blood flow will be evaluated with transcranial Doppler (TCD) during rest, mild exercise and auto-regulation testing (cerebral blood flow in cm/s1).

Study objective

We hypothesize that the decreased cardiac output in patients with severe aortic valve stenosis leads to reduced cerebral blood flow in a subset of patients which may be restored by TAVI.

Study design

Measurements will be performed at two points in time: 1) Baseline (prior to TAVI), 2) 3 months after TAVI

Intervention

TAVI

Contacts

Public
Amsterdam UMC - Locatie AMC
Wieneke Vlastra

020-5667883
Scientific
Amsterdam UMC - Locatie AMC
Wieneke Vlastra

020-5667883

Eligibility criteria

Inclusion criteria

Patients with severe aortic valve stenosis, eligible for TAVI of a native valve

Exclusion criteria

History of cerebrovascular disease (eg. TIA, stroke)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2016
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion
Date: 30-01-2019
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44893
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7495
CCMO	NL50524.018.14
OMON	NL-OMON44893

Study results