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

No registrations found.

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

# Summary

#### ID

NL-OMON21148

Source NTR

**Brief title** CAPITA

**Health condition** 

aortic valve stenosis

### **Sponsors and support**

**Primary 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.

**Source(s) of monetary or material Support:** 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.

### Intervention

### **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 ( $\Delta$  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**

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.

#### **Study objective**

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.

#### Study design

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

#### Intervention

Transcatheter aortic valve implantation (TAVI)

# Contacts

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# **Eligibility criteria**

### **Inclusion criteria**

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.

#### **Exclusion criteria**

Presence of MRI contra-indication; inability to lay flat for 30 minutes; weight > 130 kg;

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neurological presence; active malignant disease; insufficient mastery of the Dutch language; alcohol use inability to withdraw 24 hours; non-atherosclerotic vascular disease (eg vasculitis).

# Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2020
Enrollment:	142
Туре:	Anticipated

### **IPD** sharing statement

Plan to share IPD: Undecided

# **Ethics review**

Positive opinion Date: Application type:

19-06-2020 First submission

# **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
NTR-new	NL8721
Other	METC AMC : METC 2019_08, NL72247.018.19

# **Study results**