A study of neuropsychological functioning in patients undergoing aortic valve replacement: the transcatheter and the surgical approach

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To determine the effects of surgical and transcatheter (transapical, transfemoral or transaortal) aortic valve replacement on patient neuropsychological functioning which provides the opportunity to prematurely establish subclinical effects that may...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38055

Source
ToetsingOnline

Brief title
NPF in AVR

Condition

- Cardiac valve disorders
- Cognitive and attention disorders and disturbances

Synonym
cognitive dysfunctioning, neuropsychological dysfunctioning

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, Neuropsychological, Replacement, Valve

Outcome measures

Primary outcome

Neuropsychological functioning, specifically the following domains:

- executive functioning and attention

- memory

- language

- visual spatial functioning

- psychomotor speed

Secondary outcome

Degree of anxiety and depression before and after surgical/transcatheter aortic

valve replacement

Quality of life before and after surgical/transcatheter aortic valve

replacement

Study description

Background summary

Not all patients with severe aortic valve stenosis are suitable for surgical aortic valve replacement. Transcatheter aortic valve replacement, a relatively novel procedure, was developed as a suitable alternative to treat this high

risk patient population with different comorbidities. A bioprosthetic valve is inserted either via the transfemoral, transapical or transaortic route using a catheter. During deployment of the bioprosthetic valve the old valve is crushed against the aortic wall. MRI studies show that in a majority of patients this causes microdebris that reaches the brain via the carotid arteries. A recent randomized controlled trial shows that compared to surgical aortic valve replacement, the percuteous procedure is associated with significantly more cerebrovascular events. However, it is unclear what the effects are of percuteous aortic valve replacement on neuropsychological functioning and the quality of life of the patient.

Study objective

To determine the effects of surgical and transcatheter (transapical, transfemoral or transaortal) aortic valve replacement on patient neuropsychological functioning which provides the opportunity to prematurely establish subclinical effects that may positively influence quality of life.

Study design

120 consecutive patients above the age of 18 years of age with an indication and accepted for:

- transcatheter aortic valve replacement
- surgical aortic valve replacement

will be asked for participation in this single center prospective observational study shortly after acceptance for treatment.

Study burden and risks

not applicable

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

Patients above 18 years of age requiring and accepted for surgical aortic valve replacement
Patients aboven 18 years of age requiring and accepted for transcatheter aortic valve replacement

Exclusion criteria

Psychiatric comorbidity that might influence neuropsychological functioning
Physical dysfunction that might influence neuropsychological functioning

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	23-05-2012
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL37486.018.12