Detection of High Intensity Transient Signals after aortic valve replacement

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Detection of High Intensity Transient Signals as hemodynamic parameter in patients undergoing aortic valve replacement

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

Summary

ID

NL-OMON30608

Source
ToetsingOnline

Brief title
Detection of H.I.T.S.

Condition

- Cardiac valve disorders
- Central nervous system vascular disorders

Synonym
Neurocognitive Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ziekenhuis / Maatschap

Intervention

Keyword: Aortic Valve Replacement, Cardiac, High Intensity Transient Signals, Neurocognitive

Outcome measures

Primary outcome

- Detection of HITS after aortic valve replacement with determination of the

accuracy and precision of the diagnostic test.

Secondary outcome

- Optimum orientation of mechanical valves

- Origin and nature (pathogenesis)of HITS

- Postoperative depravation of H.I.T.S.

- Difference between HITS measurement in mechanical and biological valve

prosthesis

Study description

Background summary

Aortic valve replacement increases the risk of trombo embolic events. By replacing the aortic valve with either mechanical valve prosthesis or a biological valve prosthesis there are a lot of anatomical and biomechanical changes that can cause micro-emboli. These micro-emboli can be detected with transcranial Doppler ultrasonography (TCD). The detected signals either from gaseous, fluid or solid emboli are so called High Intensity Transient Signals (HITS). The hypothesis is that during and after aortic valve replacement a lot of micro-emboli are coming in existence of circulation and contribute to cognitive deficits and psychoneurological dysfunction.

Study objective

Detection of High Intensity Transient Signals as hemodynamic parameter in patients undergoing aortic valve replacement

Study design

Observational Study

Study burden and risks

The transcranial Doppler ultrasonography is a non-invasive diagnostic tool with negligible risks. The burden for the patients consists of participating in a 30 to 45 minutes during TCD and participate in 4 neurocognitive tests

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

- All patients undergoing isolated aortic valve replacement
- Replacement for acquired aortic valve disease
- INR in therapeutic range when measuring HITS

Exclusion criteria

- Concomitant procedures
- Congential lesions
- No sinus rhytm
- Carotic artery diseases
- History of cerebrovascular events (stroke as well as transient ischemic attack)
- Neurocognitive deficits and psychiatric disorder

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-03-2007
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-04-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

(Nieuwegein)

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	NL16367.060.07