

Aortic atheroma burden and cognitive dysfunction after cardiac surgery

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Aim of this study is to quantify the relationship between the extent of aortic atherosclerotic disease and neurocognitive dysfunction after cardiac surgery with the use of cardiopulmonary bypass.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30070

Source

ToetsingOnline

Brief title

POCD

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

Atherosclerosis; Cognitive dysfunction

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Er is een subsidie aangevraagd voor dit onderzoek bij de Hersenstichting Nederland.

Intervention

Keyword: Atherosclerosis, Cardiac surgery, Cognition, Epi-aortic ultrasound scanning

Outcome measures

Primary outcome

Primary: The relation between atherosclerosis of the ascending aorta and neurocognitive function at three months after surgery.

Secondary outcome

The relation between atherosclerosis of the ascending aorta and neurocognitive function at discharge, stroke, transient ischemic attack, myocardial infarction and renal failure.

Study description

Background summary

Cardiac surgery is associated with significant cerebral morbidity, i.e. stroke in about 3% of patients and neurocognitive decline in up to 50% of patients. Manipulation of an atherosclerotic ascending aorta is considered to be a major risk-factor for the development of neurocognitive dysfunction. Several studies have tried to establish the relation between the severity of atherosclerosis of the ascending aorta and deterioration of cognitive function, with conflicting results. Weaknesses in the methods used in these studies, however, make their results difficult to interpret.

Study objective

Aim of this study is to quantify the relationship between the extent of aortic atherosclerotic disease and neurocognitive dysfunction after cardiac surgery with the use of cardiopulmonary bypass.

Study design

Multicenter, observational prospective cohort study.

Study burden and risks

Patient burden is minimal, it exists of testing of the neurocognitive function at three time points (prior to surgery, at discharge and 3 months postoperative), using a computerized test battery (CogHealth, CogState Ltd., Melbourne Australia). The degree of atherosclerosis of the ascending aorta will be assessed using intraoperative epiaortic ultrasound scanning. There are no extra risks associated with participation.

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

A sub-sample of patients included in the diagnostic trial A-view: *Diagnostic value of an

innovative non-invasive diagnostic to determine the grade of atherosclerosis before sternotomy in patients scheduled for cardiac surgery*. Patients over 65 years, undergoing sternotomy for elective cardiac surgery will be included in this study.

Exclusion criteria

Patients who undergo a re-operation or off-pump surgery, suffer from neurodegenerative disease or a known psychiatric disorder and patients who are thought to be unable to perform neurocognitive testing will be excluded from participation in the subsample.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2006

Enrollment: 250

Type: Anticipated

Ethics review

Approved WMO

Date: 19-10-2006

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

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	NL13123.075.06