Perioperative assessment of cerebral ischemia in patients undergoing aortic arch surgery

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Encephalopathies
Study type	Observational invasive

Summary

ID

NL-OMON49005

Source
ToetsingOnline

Brief title
Cerebral ischemia in aortic arch surgery

Condition

- Encephalopathies
- Aneurysms and artery dissections

Synonym
Ischemia, stroke

Research involving
Human

Sponsors and support

Primary sponsor: IC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aortic arch surgery, Autoregulation, Brain, Ischemia

Outcome measures

Primary outcome

Main study parameters is the dose of cerebral ischemia.

Secondary outcome

Secondary parameters include factors that influence cerebral ischemia, such as cerebral autoregulation and neuronal activity, and effects of ischemia, such as changes in neurological and cognitive tests and delirium and biomarkers of ischemia.

Study description

Background summary

The risk of neurological complications after aortic arch surgery is high, mainly as a result of peri-procedural ischemia. Aortic arch surgery is associated with a disturbance of the normal state of cerebral autoregulation, especially during and after extracorporal circulation, deep hypothermia and circulatory arrest. The optimal cerebral perfusion pressure under these circumstances is unknown. Hypoperfusion can potentially cause a mismatch between cerebral oxygen demand and supply. Both anesthesia and hypothermia decrease the metabolic decrease the metabolic demand of the brain. Whether this decrease in metabolism is proportional to the changes in cerebral blood flow is unknown.

Study objective

The primary objective is to measure the dose of cerebral ischemia, as a measure of cerebral hypoperfusion, before, during and after aortic arch surgery. Secondary objectives include parameters that influence the occurrence of cerebral ischemia (dynamic autoregulation, cerebral blood flow velocity, arterial blood pressure, PaCO2 and PaO2, cerebral aerobic and anaerobic metabolism and neuronal activity) and the effects of cerebral ischemia on the brain (functional neurological and cognitive testing, incidence of delirium,

biomarkers of cerebral ischemia)

Study design

Observational study

Study burden and risks

The burden for the patients is minimal. Procedures related to this study are mostly non-invasive (transcranial Doppler, NIRS, and Finger photoplethysmography, with no risk. Patients <70 years need to spend an extra 15-20 minutes during the pre- and postoperative visit, during which non-invasive measurements are performed. Patients >70 years do not need to spend extra time during the visits, as they are already visiting a geriatrician. The measurements will take about 10 minutes after equipment. Some patients might experience the measurements as annoying, but the measurements do not relate to any health risk.
Peri-operative monitoring (EEG, TCD, NIRS and Jugular bulb measurements) will be continued after admission to the ICU. During the first hours of ICU admission, patients are sedated and monitoring will not cause any (additional) discomfort. Upon awakening, EEG will be discontinued. No invasive measurements will be necessary, and the burden for the patients minimal. Blood (for measurement of bloodgas and neurospecific markers) will be drawn from an arterial catheter, to a maximum amount of 20 ml in 48 hrs.
A jugular bulb catheter will be inserted at the operating theatre, together with a standard* central venous catheter in the jugular vein. Catheters will be placed by experienced anesthesiologist, under ultrasound guidance after the patient is sedated (sedation for the surgery, not for line placement). The potential risk of jugular bulb catheterization are similar to other central venous catheterizations and include hemorrhage, bleeding, arterial catheterization, pneumothorax, thrombosis and infection. These risks are estimated to be < 1%. Removal of this catheter will occur within 72 hours after insertion, thus minimizing the risk of infection or thrombosis. A jugular bulb catheter (next to a normal jugular catheter) will not cause extra discomfort for the patient; removal is without risk or burden

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

- Adult patients
- Elective aortic arch surgery

Exclusion criteria

- History of (ischemic) neurological disease, known to influence cerebral blood flow and oxygenation
- Rescue/Emergency procedure
- Failure to obtain informed consent

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2022
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL76089.091.20