Pilot-investigation: The reduction of embolic and there by neurologic complications after cardiac surgery by the use of a non-invasive imaging technique(CABG, on pump)

Published: 08-11-2010
Last updated: 18-07-2024

This pilot is meaned to obtain:- experience and understanding in the presence of new embolic load in the brain by means of DW-MRI- Understanding in the number of patients in which probably the post-operative DW-MRI can not be done according to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON34561

Source
ToetsingOnline

Brief title
A-View 3

Condition

- Structural brain disorders
- Vascular therapeutic procedures
- Embolism and thrombosis

Synonym
atherosclerosis, embolism

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Zorgvernieuwingsproject

Intervention

Keyword: atherosclerosis, A-View, cardiac surgery, embolic load

Outcome measures

Primary outcome

Will the use of the A-View method lead to a change in embolic events due to

cardiac surgery, visible on the postoperative DW-MRI by patients after CABG?

Secondary outcome

Will the use of the A-View method lead to a reduction in the number of patients

with delirium and cognitive dysfunction after CABG surgery

How often will the diagnostic information of the A-view method lead to a change

in surgical policy

Study description

Background summary

Patients undergoing cardiac surgery frequently develop neurologic complications, ranging from subtle cognitive changes to evident confusion, delirium, and stroke. This continuum of complications is commonly caused by embolization in the brain due to manipulation of atherosclerotic parts of the aorta ascendens (AA) during surgery. Timely detection of AA atherosclerosis before surgery enables the surgeon to consider changes of the surgical plan, to reduce the risk of embolization and thus subsequent neurologic complications. Various methods exist to visualize the AA to detect atherosclerosis. Epiaortic ultrasound scanning has become the gold standard, but is seldom used as it

affacts often to late the surgical plan and it can only be used after sternotomy , it increases the change of an infection of the sternum. Transesophageal echocardiography (TEE) is a widely used imaging method permitting evaluation of the aorta preoperatively, but assessment of distal AA is hampered by interposition of air-filled trachea between oesophagus and AA. The A-View® (Aortic-view) method, a modification of conventional TEE using a fluid-filled balloon, overcomes this limitation. The safety and diagnostic accuracy of the A-View® have successfully been shown in previous studies. This study is the logical next step to investigate more whether the use of the A-View® method effectively reduces embolic load in the brain and thereby neurologic complications.

Study objective

This pilot is meaned to obtain:
- experience and understanding in the presence of new embolic load in the brain by means of DW-MRI
- Understanding in the number of patients in which probably the post-operative DW-MRI can not be done according to clinical complications (like agitation, etc.)
After a successful pilotstudy a mainstudy will be done with 240 patients.
The objective of this mainstudy is to investigate whether use of the A-View® method effectively reduces embolic load in the brain and thereby neurologic complications in patients undergoing on-pump cardiovascular artery bypass grafting (CABG) surgery.

Study design

The A-view 3 study is a single-center randomized pragmatic trial in which patients referred for elective CABG surgery with the use of cardiopulmonary bypass (CPB) will be allocated to either CABG surgery with the use of the A-View® method (intervention group) or receive care as usual (i.e., without use of the A-View® method, control group).
In the patients randomized to the intervention group the presence of aortic atherosclerosis will be investigated by the treating anaesthesiologist before opening the sternum, first using conventional TEE conform standard care and subsequently with the A-View® method. The TEE plus A-View® results will be discussed with the surgeon. Based on these results, adaptation of the treatment strategy will take place according to a predefined protocol. Possible adaptation strategies range from no adaptation to minor (e.g., different position of the aortic canula; single cross clamp in stead of side biting clamp for proximal anastomosis), moderate (e.g., different type of aortic canula; Off-Pump CABG), or major (e.g., hypothermic circulatory arrest with aortic ascendens replacement; fibrillating CABG with no use of aortic cross clamp at all; proximal anastomis stapler) surgical changes, dependent on the stage and location of atherosclerosis.

The control group receives care as usual, i.e. regular TEE monitoring without the A-View®method. Surgical strategy is determined conform current care.

Procedure. After written informed consent is obtained, a pre-surgery DW-MRI scan of the brain will be made to determine the number, size and location of lesions present before surgery. Also, Quality of Life and neuropsychologic tests will be performed as part of the preoperative work-up. Before sternotomy, the presence of aortic atherosclerosis will be investigated according to the randomization group, as described above. After surgery the patient is treated according to standard care, i.e., admission to the ICU and subsequent discharge to the ward when possible. Between 3 and 7 days postoperatively, a second DW-MRI scan of the brain is performed. During ICU and hospital stay, delirium is measured according to standardized scoring instruments (ICU: Neecham*s scale; ward: Delirium Observation Scale). All major complications are registered during hospital stay and neurologic complications will be registered up till 6 weeks after surgery. At six weeks post-surgery the patient will undergo the second series of neuropsychologic tests to investigate remaining cognitive decline and at 6 weeks Quality of Life measurement.

Intervention

Procedure. After written informed consent is obtained, a pre-surgery DW-MRI scan of the brain will be made to determine the number, size and location of lesions present before surgery. Also, Quality of Life and neuropsychologic tests will be performed as part of the preoperative work-up. Before sternotomy, the presence of aortic atherosclerosis will be investigated according to the randomization group, as described above. After surgery the patient is treated according to standard care, i.e., admission to the ICU and subsequent discharge to the ward when possible. Between 3 and 7 days postoperatively, a second DW-MRI scan of the brain is performed. During ICU and hospital stay, delirium is measured according to standardized scoring instruments (ICU: Neecham*s scale; ward: Delirium Observation Scale). All major complications are registered during hospital stay and neurologic complications will be registered up till 6 weeks after surgery. At six weeks post-surgery the patient will undergo the second series of neuropsychologic tests to investigate remaining cognitive decline and at 6 weeksa Quality of Life measurement.

Study burden and risks

The hypothesis underlying this study is that the use of the A-View® method in cardiac surgery patients provides better insight in the presence and grade of AA atherosclerosis, at a timely moment to enable the surgeon to change his/her therapeutic management. These changes - from moderate (site of aortic cannulation or clamping) to extensive (conversion to off-pump CABG or aortic ascendens replacement) - are hypothesized to reduce the risk of embolization in the brain. These induced embolizations will be visualized by means of a pre-

and postoperative diffusion-weighted magnetic resonance imaging (DW-MRI). The burden is additional diagnostic tests such as MRI. The advantage is timely change of surgical strategy in order to prevent cerebral infarction.

Contacts

Public
Isala Klinieken

Groot Wezenland 20
8011 JW
NL
Scientific
Isala Klinieken

Groot Wezenland 20
8011 JW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All on pump CABG patients who have a relatively high risk of neurologic complications, as identified by the Stroke Risk Index, and who also have signed an informed consent.

Exclusion criteria

Patients with contra-indications for TEE (e.g. esophageal pathology or hiatal hernia) or for the A-View® method (e.g. severe COPD, tracheal dysfunction) are excluded. Similarly, patients in whom no MRI can be made (e.g. with external pacemaker or claustrofobia) are also excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	A-view catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-11-2010
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	NL32122.075.10