Cerebral Micro-emboli Detection after Cardiac Surgery (A prospective follow-up study)

Published: 19-11-2018
Last updated: 16-11-2024

To demonstrate the added value of TCD emboli detection in patients after cardiac surgery. To investigate the possibility of an early detection of silent cerebral embolization after a cardiac surgery procedure to identify a subset of patients with an...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON55775

Source
ToetsingOnline

Brief title
CMD

Condition

- Other condition
- Cardiac therapeutic procedures

Synonym
micro emboli signal, stroke

Health condition

neurologische complicaties na hartchirurgie

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: subsidie is aangevraagd bij het wetenschapsfonds van het HagaZiekenhuis

Intervention

Keyword: cardiac surgery, micro emboli, TCDx

Outcome measures

Primary outcome

development of a CVA till two weeks after cardiac surgery

Secondary outcome

1. The severity and type of the post-operative CVA till two weeks after cardiac

surgery

2. Occurrence of delirium till two weeks after cardiac surgery

3. Kidney failure till two weeks after cardiac surgery

4. Sepsis till two weeks after cardiac surgery

5. Mortality till two weeks after cardiac surgery

Study description

Background summary

Occurrence of Embolic CVA's after heart surgery is a result of slipping thrombi caused by surgery vascular wall and heart valve damage. These sources of embolism during and after a CABG is particular caused by the mechanical damage of the great vessels. For valve replacement is particularly the implanted valve a potential source of thrombus formation. Also arrhythmias activate already present embolism sources. Atrial fibrillation (AF) is a known risk factor for post-operative embolic CVA (so Paroxysmal AF can be a trigger for a cerebral embolism from a pre-existent thrombus in the left heart ear).
The incidence of embolic CVA after heart surgery depends on the type of surgery. The chance of a STROKE after CABG is in the Dutch cardiac surgery

centers between 0.3% and 1.3%. For aortic and mitral valve replacement is the rate between 0.3% and 2.1%, while in a combined procedure (valve replacement and CABG) the highest rates are observed (between 0.3 and 2.8%). Apparently, complexity of the surgery has a relationship with the occurrence of a CVA.
The occurrence of a Embolic CVA after heart surgery is difficult to predict because there is no simple method is to detect the instability of vascular lesions. Heart rhythm disorders are easy to detect by ECG, but the predictive value of AF on causing an embolic CVA is very low because AF occurs also in patients with stable vascular lesions.
In recent years, a technique is developed to detect indirectly unstable lesions in patients: the TCD emboli detection. With TCD it is possible to detect, on a non-invasive way, the cerebral embolism of originally unstable vascular wall lesion. Assuming of the possibility to detect asymptomatic cerebral micro emboli hours to days before a stroke, TCD emboli detection is a method that potentially could be used to shows an increased risk of postoperative embolic CVA. When it is possible with TCD emboli detection to identify a group of patients with a high risk for post-operative embolic CVA after a heart surgery at an early stage, it is possible to develop a strategy for high risk patients to perform an intervention for reducing the risk on a post-surgery CVA.

Study objective

To demonstrate the added value of TCD emboli detection in patients after cardiac surgery. To investigate the possibility of an early detection of silent cerebral embolization after a cardiac surgery procedure to identify a subset of patients with an increased risk of a post surgically embolic CVA.

Study design

A prospective observational study with a TCD Holter monitor (TCDx) in patients in the early postoperative phase after heart surgery or TAVI. The TCDx investigation will be done in the first 4 hours after the surgery when the patient is hospitalized on the Intensive Care unit (ICU).

Study burden and risks

This study will be provide information if TCD emboli detection can be used in risk stratification of the occurrence of a embolic CVA. There are no advantages or disadvantages for the patient. TCD research is an easy-to-use non-invasive analysis of the cerebral blood stream by ultra sound.

Contacts

Public

HagaZiekenhuis

Els Borst-Eilersplein 275
Den Haag 2545 AA
NL
Scientific
HagaZiekenhuis

Els Borst-Eilersplein 275
Den Haag 2545 AA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

patients after TAVI or valve replacement with or without CABG surgery
written Informed consent to participate
mentally competent
18 years and older

Exclusion criteria

recentlyTIA of CVA
Kidney dialysis
language barrier

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	30-04-2019
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	19-11-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	15-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL66304.098.18