

# Microemboli in Aortic Valve Surgery: Minimized Extracorporeal Circulation vs. Classic Extracorporeal Circulation.

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This study is performed to assess the effect of MECC system compared to CECC in patients undergoing aortic valve surgery on microemboli in the form of high intensity transient signals (HITS) detected by Transcranial Doppler Ultrasonography (TCD)....

|                              |                         |
|------------------------------|-------------------------|
| <b>Ethical review</b>        | Approved WMO            |
| <b>Status</b>                | Recruitment stopped     |
| <b>Health condition type</b> | Cardiac valve disorders |
| <b>Study type</b>            | Interventional          |

## Summary

### ID

NL-OMON33526

### Source

ToetsingOnline

### Brief title

Microemboli in Aortic Valve Surgery : MECC vs. CECC

### Condition

- Cardiac valve disorders
- Cognitive and attention disorders and disturbances
- Vascular therapeutic procedures

### Synonym

neurocognitive deficit, Stroke

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Sint Antonius Ziekenhuis

**Source(s) of monetary or material Support:** De extra kosten worden betaald door de Schaepekens van Riemst stichting en de firma Marquet ( Jostra).,Jostra AB, Sweden

## Intervention

**Keyword:** Aortic Valve Surgery, MECC, Mircoemboli, Quality of life

## Outcome measures

### Primary outcome

The primary end point for the study will be the number of high intensity transient signals (HITS) as detected by the TCD during the procedure. Adjacent to HITS the consumption of blood products will be the main study parameter

### Secondary outcome

Secondary Objective(s):

To evaluate the impact of the minimized extracorporeal circulation (MECC) on :

Quality of life ( SF 12 )

Cerebrovascular accident

Transient ischemic attack

Myocardial infarction

Mortality

Bleeding

Coagulation

Transfusion

Inflammatory response

Re-admission

SDF-imaging

Neuropsychological functioning

MRI brain

Organ damage ( Cardiac, Renal, Intestinal, Liver)

Cerebrale Oxymetrie

Fluidbalance

## Study description

### Background summary

Microemboli are an important risk factor for neurological damage after cardiac surgery. The cause of the neurological damage in cardiac surgery is multifactorial. The extracorporeal circulation circuit (ECC) is one of the primary causes of microemboli during operation. Minimized extracorporeal circulation (MECC) is developed in attempt to reduce this and other side effect of ECC. The MECC system is associated with a significant reduction in embolic count measured with Transcranial Doppler (TCD) monitoring during coronary bypass surgery compared to conventional ECC (CECC). Patients undergoing aortic valve surgery are at higher risk for developing a stroke and therefore reduction of the microemboli could improve the neurologic outcome after aortic valve surgery. Beside neurological complications extracorporeal circulation effects the inflammatory respons and bloodloss.

We hypothesize that the use of the MECC system in patient undergoing aortic valve surgery is associated with and a reduction in HITS determined by TCD, a reduction in the transfusion of RBC and FFP and a better QOL.

### Study objective

This study is performed to asses the effect of MECC system compared to CECC in patients undergoing aortic valve surgery on microemboli in the form of high intensity transient signals (HITS) detected by Transcranial Doppler Ultrasonography (TCD). Adjacent to the detection of microembolization with intra operative bilateral TCD, the QOL and neurocognitive functioning will be assessed in both groups. To complete the MRI of the brain will be used to identify new cerebral ischemic areas.

Next to the neurocognitive analysis the circulation and inflamatory respons will be assessed with peri-operative with Side Stream Dark Field -imaging (SDF), quantification of the transfusion of bloodproducts ( RBC and FFP) and

organ specific biomarkers.

## **Study design**

This is a prospective, randomized trial to evaluate the effect of two applied cardiopulmonary bypass techniques, minimized extracorporeal circulation (MECC) versus conventional cardiopulmonary bypass in patients undergoing aortic valve replacement on the intraoperative high intensity transient signals (HITS) detected by Transcranial Doppler ultrasonography (TCD).

Beside HITS determination for emboli detection neurocognitive analysis take place with a Quality of Life assessment, neuropsychological analyses.

Next to the neurocognitive analysis the circulation and inflammatory responses will be assessed with peri-operative with Side Stream Dark Field -imaging (SDF), quantification of the transfusion of bloodproducts (RBC and FFP) and organ specific biomarkers. Patients undergoing aortic valve replacement meeting the inclusion criteria will be enrolled. Comparative and descriptive statistics will be used to summarize patient outcomes for specific study endpoints

## **Intervention**

One group of patients will undergo aortic valve replacement with the minimized extracorporeal circulation (MECC) and the other group of patient will be treated with the CECC.

### **Minimized Extra Corporeal Circulation**

The MECC system consist of a closed system containing a centrifugal pump ( Rotaflow; Jostra) and a membrane oxygenator (Quadox HE;Jostra). The Venous line is connected to the centrifugal pump via a venousbubble trap (VBT 160). All components are Bioline coated ( Jostra). Priming volume of the system is 700 ml of NaCl 0,9 % ( this solution contains 14.4. % hydroxyethyl starch). Retrograde autologous priming is used in hemodynamical stable patients. Myocardial protection is performed by using a modified Calafiori technique. (potassium blood cardioplegia every 15 - 20 minutes) Blood from the surgical field will be collected by a cell-saving device (BRAT 2; Cobe). Anticoagulation is attained by administration of 150 IU/KG heparin to achieve an activated clotting time of longer than 300 seconds. The left ventricle is vented via a vent in the pulmonary artery. Continuous carbondioxide (CO2) insufflation is used during the procedure. Dexamethasone (1mg/kg) was administrated at induction of the anesthesia.

### **Conventional Extra Corporeal Circulation**

The ECC closed circuit is composed of a centrifugal pump (Jostra), a hollow -

fiber polypropylene oxygenator (CTRBE-HMO 1010; Jostra) , a venous reservoir (BMR 1900G; Jostra), a cardiotomy reservoir ( Quadrox BE-AC2811;Jostra), and Rehau Bioline-coated tubing ( Maquet/Jostra). The pump is primed with 1600 mL. Myocardial protection is performed by using a modified Calafiori technique (blood cardioplegia every 15 -20 minutes.) Anticoagulation was attained by administration of 300 IU/KG heparin to achieve an activated clotting time of longer than 400 seconds. Blood from the surgical field will be drained to the venous reservoir. Left ventricle is vented via a vent in the right upper pulmonary vein. Continuous carbondioxide (CO2) insufflation is used during the procedure. Dexamethasone (1mg/kg) was administrated at induction of the anesthesia.

## **Study burden and risks**

There is no expected associated risk with participation in this trial. Both CECC and MECC are successfully performed in the St. Antonius Hospital. Patients will ask to fill out the 12 questionnaire pre-operative, at 3 months and 6 months postoperative. Neuropsychological testing will be performed pre-operative, at discharge and at 3 and 12 month postoperative. Microcirculation assessment is performed during the operation and direct postoperative and is performed without discomfort for the patient. Blood analysis is part of standard procedure pre and postoperative treatment. Extra blood investigations will be embedded in these standard analyses. TCD is not a standard procedure during aortic valve replacement. TCD is performed during the procedure while the patient is under general anaesthesia and terminates at the completion of the procedure. Therefore we anticipate no physiological and physical discomfort with participation. Diffusion weighted MRI is done preoperative and at discharge and is not part of routine patient care.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- 1.The patient must be between 18-80 years of age.
- 2.Patients scheduled for elective aortic valve surgery or combined coronary with aortic valve surgery
- 3.The patient is mentally able and willing to give informed consent.

### Exclusion criteria

1. Emergency operation
2. Active endocarditis
3. Double valve procedure.
4. Operation on the aortic root.
5. Very poor left ventricular function (EF < 20 %).
6. Previous cardiac surgery.
7. Dialysis dependent renal failure.
8. Internal carotid artery stenosis of 50% or greater.
9. Illeracy or nonfluency in dutch.
10. Absence of auoustic window for TCD monitoring
11. Contraindications for MRI (electronically, magnetically, and mechanically activated implants [Pacemaker,nervestimulator, Insulin pumps etc], metallic splinters, claustrophobia, cochlear implants and ferromagnetic mechanical stapedial replacements, clips in the central nervous system (CNS) ).

## Study design

## Design

|                     |                             |
|---------------------|-----------------------------|
| Study type:         | Interventional              |
| Intervention model: | Parallel                    |
| Allocation:         | Randomized controlled trial |
| Masking:            | Open (masking not used)     |
| Control:            | Active                      |
| Primary purpose:    | Diagnostic                  |

## Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 15-12-2008          |
| Enrollment:               | 100                 |
| Type:                     | Actual              |

## Ethics review

|                    |                                                               |
|--------------------|---------------------------------------------------------------|
| Approved WMO       |                                                               |
| Date:              | 10-06-2008                                                    |
| Application type:  | First submission                                              |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO       |                                                               |
| Date:              | 21-04-2009                                                    |
| Application type:  | Amendment                                                     |
| 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     | NL16195.100.07 |