Administration of warm blood cardioplegia with or without roller pump; a comparison.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON37560

Source
ToetsingOnline

Brief title
Pumpless blood cardioplegia

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
CABG, coronary artery bypass grafting

Research involving
Human

Sponsors and support

Primary sponsor: Heartbeat
Source(s) of monetary or material Support: Heartbeat

Intervention

Keyword: blood cardioplegia, myocardial injury, roller pump

Outcome measures

Primary outcome

Perioperative myocardial injury, reflected by biomarker release:

- Troponin I

- hFABP

- NT-pro-BNP

Secondary outcome

- Post-operative myocardial infarction: rise of troponin above the 99th percentile together with evidence of myocardial ischaemia (symptoms of ischaemia or ECG changes)

- Cardioplegia bloodflow measured with Em-Tec

- Pressure in aortic root during blood cardioplegia administration

- Line pressure cardioplegia

- Total Potassium chloride/Magnesium sulfaat (ml)

- Serum potassium level patient after aortic declamping

- Longest interval of blood cardioplegia (min)

- Mean interval of blood cardioplegia (min)

- ECG activity during aortic occlusion

- Number of blood cardioplegia gifts

- Intra-operative inflammatory respons, refelcted bij CRP level.

- Number of anastomosis

- ECC time (min)

- Aortic occlusion time (min)

- Number of defibrillation after aortic declamping

- Inotropic support (hours)

- Post-operative complications (TIA/CVA, pneumonia, renal failure

(createnine>177), re-thoracotomy, atrial fibrillation)

- Length of ICU stay

- Length of hospital stay

Study description

Background summary

Over the last decade, warm blood cardioplegia is infused with a roller pump according to the modified calafiori technique. Blood cardioplegia can also be delivered without the use of a roller pump, but with the use of the arterial line pressure as created by the arterial centrifugal pump of the cardiopulmonary bypass system. This technique is currently applied in some clinics in the Netherlands and probably in more clinics world-wide. The elimination of a roller pump might be a step towards the reduction of heart-lung machine hardware. The use of a mini heart-lung machine may become available for future use in cardiac surgery. Besides the avoidance of a roller pump, an advantage of this method may be that the flow of the blood cardiolegia will be dynamic. The flow of the blood cardioplegia will be influenced by the functional status and the size of the patients* heart.

Study objective

The aim of the study is to evaluate the effect of warm blood cardioplegia administration without rollerpump on perioperative myocardial injury in patients undergoing coronary artery bypass grafting (CABG) with a minimal extracorporeal circuit (MECC).

Study design

The design of the study is a randomized controlled trial.

Intervention

After informed consent, patients will be randomized into study group (blood cardioplegia administation without roller pump) or control group (blood cardioplegia administration with roller pump).

Study burden and risks

There is no expected associated risk with participation in this study. Both administration techniques of warm blood cardioplegia are standard treatments and are successfully performed world wide. Blood samples will be taken after anaesthetic induction (T0), after arrival ICU (T1), 4 hours in ICU (T2) and first day post-operative (T3). The patient*s discomfort is therefore limited.

Contacts

Public
Heartbeat

Patrijzenhof 102
3755 EV Eemnes
NL
Scientific
Heartbeat

Patrijzenhof 102
3755 EV Eemnes
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Patients undergoing elective coronary artery bypass grafting
- At least 3 distal anastomosis will be performed

Exclusion criteria

- Previous cardiac surgery
- Left ventricular ejection fraction <45%
- Chronic renal failure, defined by preoperative creatinine > 177 ug/ml.
- Aortic Insufficiency, >= grade 1

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2012
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO

Date:	17-07-2012
Application type:	First submission

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	NL40335.100.12