A comparison of the use of mini extracorporeal circuits with conventional extracorporeal circuits and with further miniaturized mini extracorporeal circuits in CABG patients.

Published: 07-07-2009
Last updated: 05-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33236

Source
ToetsingOnline

Brief title
A comparison of different extracorporeal circuits in CABG patients.

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
1 coronary artery bypass surgery 2 atherosclesis

Research involving
Human

Sponsors and support

Primary sponsor: Maquet cardiopulmonary
Source(s) of monetary or material Support: industrie voor medische hulpmiddelen

Intervention

Keyword: cabg, mini extracorporeal circuit (MECC)

Outcome measures

Primary outcome

Primary goal

The primary goal is to evaluate whether the use of miniaturised systems reduces

the need for homologous blood transfusions.

Secondary outcome

Secondary goal

The secondary goal is to evaluate whether the use of miniaturised systems

reduces the time to extubation post-operatively. To this end an early

extubation protocol is used to standardize the extubation process.

Study description

Background summary

A conventional extracorporeal circuit, a mini extracorporeal circuit and a further miniaturized mini extracorporeal circuit are compared in a prospective randomized clinical.
The oxygenator in the miniaturized mini extracorporeal circuit has been improved leading to a decrease in the blood contact surface area and priming volume.
To compare blood usage, biocompatibility and clinical outcome of these three

circuits, one hundred and fifty patients undergoing coronary artery bypass grafting will be randomly allocated into groups to be perfused with one of these circuits. In all cases the autotransfusion cell separator will be used to process the mediastinal shed blood and residual pump blood.
The groups will be compared with each other, in relation with blood cells (PLT, WBC, RBC), acute phase response (CRP), kidney injury (Urea, Creatinine) cardiac injury (CPK-MB, Troponin), ischemia (Lactate), and cardiac electrical activity.

Study objective

This study will evaluate if the use of a mini extracorporeal circuit is an improvement for the patient.
The study investigates how much the use of a mini extracorporeal circuit will change the homologous blood requirements and the magnitude of the inflammatory response. We assume that the inflammatory response will be less obvious when we use the mini extracorporeal circuit by reduction of the blood contact surface area and the prime volume. Reduction of hemodilution and the inflammatory response may lead to reduction in the use of homologous blood products and less organ damage, which also means reduction of costs.

Study design

The study will be performed in a non-academic centre for cardiac surgery, by means of a clinical prospective study of 150 patients divided in three groups; a conventional extracorporeal circuit, the mini extracorporeal circuit (MECC) and a group with a further miniaturised mini extracorporeal circuit (MMECC). Randomisation of the patients will be performed by the following action: The day before the surgery an independent person will open an envelope, containing a treatment form. On the form the date of randomisation and the unique patient hospital number will be marked. The same day the perfusionist will be informed for the construction of the appropriate ECC circuit.

Study burden and risks

The possible risk of an incident with the MECC and MMECC circuit is not significantly different compared with the conventional ECC circuit.
The potential benefit of the use of the MECC and MMECC circuit is the reduction of homologous blood transfusion with all its risks.

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

* To have the right indication.
* Body surface area between 1.7 and 2.0 m^2.
* Age 20-80.
* Pre-operative normal sinus rhythm and AV-conduction time.
* Pre- operative haemoglobin > 6.5 mmol/L.
* Patient must be able to give written informed consent

Exclusion criteria

* Transfusion of blood products shorter than seven days before the operation.
* Re- operations
* Coagulation problems due to the use of thrombolytic agents less than 48 hours before the operation.
* Thrombocytopenia (platelet count below 100,000 per ml)
* Patient with hereditary hematological/ coagulation disorders
* Insulin dependent diabetes
* Using corticosteroid medication, use of corticosteroids before the surgery, or during the

study period.
* Emergency surgery
* History of atrial fibrillation or other atrial arrhytmias eg (1 ° block, paroxysmal atrial tachycardia, atrial flutter)
*Use of aspirin within 7 days or Plavix within 5 days or other anti platelet agents (including non steroid anti-inflammatory medicaments) within 48 hours.
* Patients who are currently (within the last two months) participating in another clinical trail.

Study design

Design

Study type: Observational non invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	07-07-2009
Application type:	First submission
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	NL26418.098.09