Comparison of different retransfusion strategies in cardiothoracic surgery

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1. Which of the three retransfusion techniques based on hemoconcentration (centrifugation, ultra filtration or cell separation) leads to a reduction in homologous blood transfusions as compared to control (retransfusion of diluted blood)?2. Which of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON32819

Source
ToetsingOnline

Brief title
Retransfusion strategies during cardiothoracic surgery

Condition

- Cardiac therapeutic procedures

Synonym
Coronary artery bypass graft surgery

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood transfusion, Cardiopulmonary bypass, Coagulation disorders, Retransfusion

Outcome measures

Primary outcome

Number of homologous bloodtransfusions after cardiopulmonary bypass.

Secondary outcome

Demographic variables: Age, gender, length, body weight, preoperative and

postoperative hematocrit, hemoglobin, leukocyte count, IL-6 & DPG.

Surgical characteristics: Surgery time, clamp time, CPB time, blood loss,

arterial gasses pre-, intra- and postoperatively.

Study description

Background summary

Intra- and postoperative bleeding in patients undergoing cardiac surgery is a major complication which may lead to homologous blood transfusions and postoperative complications. After cardiopulmonary bypass (CPB), a residual blood volume remains in the heart-lung machine, which may be retransfused to the patient in order to normalize blood volume and coagulation. However, retransfusion of diluted blood is inefficient, since it has low hematocrit and coagulation properties. Concentration of this residual blood volume may enhance its hematocrit and coagulation properties such that the need for homologous blood transfusions in these patients is reduced. The present study therefore aims to compare three blood concentrating techniques with the standard retransfusion technique in order to establish an optimal retransfusion strategy for patients that may reduce the number of homologous blood transfusions.

Study objective

1. Which of the three retransfusion techniques based on hemoconcentration (centrifugation, ultra filtration or cell separation) leads to a reduction in homologous blood transfusions as compared to control (retransfusion of diluted blood)?
2. Which of the three retransfusion techniques lead to a reduction in

pro-inflammatory markers and an increase in coagulation proteins as compared to control?

Study design

Single-center prospective randomized controlled intervention study

Intervention

Use of different hemoconcentration retransfusion techniques after cardiopulmonary bypass.

Study burden and risks

Residual blood of the heart-lung machine is normally directly retransfused in CABG patients. A disadvantage of this technique is that the residual blood volume is highly diluted thereby leading to retransfusion of blood with a low hematocrit and poor coagulation properties. As a consequence, most patients receive additional homologous blood transfusions, which may alter the risk for infections and activation of inflammatory pathways. Patients will be randomized to four different groups: A) control group (retransfusion of diluted blood), B) centrifugation group, C) ultra filtration group and D) cell-separation group.

Blood sampling
For this study, a total of 10 ml of blood will be drawn while the patient is under anesthesia. This will not add up to patient discomfort.

Control patients
Control patients will receive standard clinical care (retransfusion of diluted blood). Since this treatment modality does not differ from routine clinical care, it will not add up to patient discomfort and risk. However, it is expected that this group of patients has a higher need for homologous blood transfusions as compared to the hemoconcentration groups, thereby increasing the risk for inflammation and infection.

Hemoconcentration
Hemoconcentration techniques are legally and clinically approved for concentration of residual blood volumes. The application of hemoconcentration may reduce the need for homologous blood transfusion, which might be beneficial for the patient. Since the hemoconcentration techniques are clinically validated and safe, the use of these devices will not add up to patient discomfort.

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

Patients undergoing coronary artery bypass surgery (CABG)
Use of cardiopulmonary bypass (CPB)
Age 18-75 years
Informed consent

Exclusion criteria

Re-operations
Patient with hereditary hematological/coagulation disorders
Emergency operation
Body surface area (BSA) 1.7 < BSA > 2.3

Patient with anemia (Hb < 6.0)
Patients receiving blood transfusions < 3 months before operation
Patients receiving blood transfusion before or during extracorporeal circulation
Insulin depended diabetes mellitus
Patients who are currently participating in another clinical trial

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2008
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO

Date:	27-11-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL24180.029.08