Does have autologous blood withdrawal pre-operative with and without sequestration, effect on the usage of allogeneic bloodproducts during and after heartsurgery.

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

Summary

ID

NL-OMON33597

Source
ToetsingOnline

Brief title
Sequestration Study

Condition

- Cardiac therapeutic procedures

Synonym
Need for blood transfusion during and after open heart surgery

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CPB, Open Heart Surgery, Sequestration, Transfusion need

Outcome measures

Primary outcome

Is there a decrease in use of allogeneic blood products in the sequestration

group?

Secondary outcome

Is there a decrease of blood loss in the sequestration group in regards to the

blood loss of the other two groups?

Study description

Background summary

Preoperative, during induction of anaesthesia, autologous blood is withdrawn and afterward is given back after cardio-pulmonary-bypass (CPB), because of the presumed benefit on haemostasis.
The consequence of the blood withdrawal before CPB is not seldom low Hematocrit (Ht) during bypass and allogeneic red blood cells (RBC*s) need to be added to gain a target level of Ht.
Transfusion of RBC*s could be avoided when sequestration of the autologous blood is applied. During sequestration blood cells are separated from the plasma.
The autologous RBC*s will be given back to the patient immediately after withdrawing; the platelets and plasma can be given to the patient after CPB cessation and protamine administration.
To examine the results of autologous blood withdrawal on patients with a normal Hb/Ht a prospective, randomized study will be performed.
The hypothesis is that sequestration of autologous blood will result in less transfusion of allogeneic blood products.
Primarily will be investigated the amount of allogeneic blood products

transfusion and the coagulation of the patient.
When the outcome will be positive: the treatment can be in the follow-up study validated for the patient with a smaller body surface.

Study objective

When it is possible to prove that there is a significant difference between the sequestration group and the other two groups, it also will be possible for patients with a smaller body surface to donate autologous blood and also this group will need also less allogeneic blood products.

Study design

There will be 3 groups of patients.
Each group will consist of 34 patients.
Group 1. autologous blood withdrawal.
Group 2. autologous blood withdrawal with sequestration.
Group 3. control group
In group 1 autologous blood is withdrawn during induction of anesthesia and is given back to the patient after administration of protamine. Till that time it will be kept on good condition on 37 degrees Celsius.
In group 2 autologous blood is withdrawn and sequestration will take place immediately. After sequestration the RBC will be given back to the patient; the plasma and platelets will be given back to the patient after CPB and will be kept on a gentle shaker.
In group 3 there will be no withdrawing of autologous blood.
In all groups the rest volume will be handled the same with auto transfusion apparatus as usually.
The volume what is declined is replaced by colloid solution.

Intervention

Group 1. autologous blood withdrawal and return transfusion.
Group 2. autologous blood withdrawal with sequestration and return transfusion.
Group 3. control group

Study burden and risks

Load:
Extra time to explain and inform the patient of this study and for signing the informed consent.
Risk:
No extra risk.

Contacts

Public
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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adults age >= 18 year, undergoing openheartsurgery for CABG and or valve surgery
BSA > 170 dm2
Hemoglobin/Hematocrit >= 0,20 L/L

Exclusion criteria

Pre-operative Total Trombocytes < 120 x 109/L
Pre-operative increased liver enzymes: ASAT, ALAT, AF >= 2,5 x ULN
NYHA Class III and IV
Severe impaired renal function: Creatinine > 120 umol/l
Re operation

COPD

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2009
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO

Date:	12-05-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL26000.078.08
Other	NTR candidate nummer 4740