Does have autologous bloodwithdrawal with or without sequestration effect on the usage of allogeneic bloodproducts during heartsurgery?

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26094

Source
Nationaal Trial Register

Brief title
Sequestration Study

Health condition

heartsurgery
CPB
autologous bloodwithdrawal
sequestration
allogeneic bloodproducts

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Will the usage of allogeneic bloodproducts be deminished after sequestration?

Secondary outcome

Is the total amount of bloodloss in the sequestration group less compared to the total amount of bloodloss in the other groups?

Study description

Background summary

Background of this study:

Preoperative, during induction of anaesthesia, autologous blood is withdrawn and afterward is given back after cardio-pulmonary-bypass (CPB), because of the presumed benefit on haemostasis.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.

Purpose of this study:

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 set-up:

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.

Study population:

Inclusion criteria:

1. >18 years;

2. body surface > 170 dm2;

3. Primary CABG and/or AVR procedure;

4. Hb/Ht level which will be no lower than
0.20 l/l after calculation for autologous blood withdrawing.

Exclusion criteria:

1. trombocytes count of <120(x109/l).

Pre operative:

1. increased liver enzymes (ALAT/ASAT/AF);

2. very poor Left Ventricle function;

3. impaired renal function (Kreatinine of >120 mmol/l;

4. COPD;

5. Reoperation.

Primary study variables/results:

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

Secondary examination result:

Is there a decrease of blood loss in the sequestration group in regards to the blood loss of the other two groups?

Description and estimation of load and risks:

Load:

Extra time to explain and inform the patient of this study and for signing the informed

consent.

Risk:

No extra risk.

Study objective

We expect that after autologous bloodwithdrawal followed by plasma sequestration before the autologous transfusion, the usage of allogeneic bloodproducts will be deminished.

Study design

Induction, return of RBC immediately after sequestration, return of trombocytes at the end of CPB.

End time operation, time point 4 hours after entry ICU. Removal drains.

Intervention

Group 1:

autologous bloodwithdrawal (500ml-1000ml) during induction of anesthesia.
The blood will be saved in bloodbags Compoflex (Fresenius). These bloodbags will contain CPDA (citrate-phosphate-dextrose-adenine) necessary to prevent soldification of the autologous blood. Blood will be kept on the "shudder" at 37 degrees Celcius until the end of the CPB. After CPB it will be given back (autologous transfusion) after administration of protamine.

Group 2:

autologous bloodwithdrawal (500ml-1000ml) during the induction of the anesthesia. Immedialely followed by sequestration and return of the RBC. The plasma and Trombocytes will be given back to the patient after CPB. This blood will be kept in bloodbags Compoflex (Fresenius). These bloodbags will contain CPDA (citrate-phosphate-dextrose-adenine) necessary to prevent soldification of the autologous blood. By this sequestration group, blood will be prepared with the autotransfusion apparatus Electa(Sorin Group). With the help of a seqestration set Trombocytes will be kept on the "shudder" (a gently shaker).

Group 3:

control group (no autologous blood withdrawal).

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Eligibility criteria

Inclusion criteria

1. Patients with a BSA > 170 dm2;

2. Patients who need to undergo CABG and or Valve surgery;

3. Patients with a Hemoglobin/Hematocrit ratio >0.20 l/l after calculation with the formula for bloodwithdrawal.

Exclusion criteria

1. Patients with a Hemoglobin/Hematocrit ratio < 0.20 l/l after calculation with the formula for bloodwithdrawal;

2. Patients with a preoperative Trombocyt count of < 120 (x109/L);

3. Patients with increased liverenzymes (ALAT/ASAT/AF > 2,5 ULN);

4. Patients with a moderate or poor left ventricle function;

5. Patients with impaired renal function (Kreatinine >120 (umol/l);

6. Patients who need to have a reoperation;

7. Patients with COPD.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	102
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1519
NTR-old	NTR1589
Other	: Thchoz 2008-11
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

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