Quality assessment of cell saved blood.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23212

Source
NTR

Brief title
Quality assessment of autotransfusion

Health condition

- coagulopathy
- inflammation

Sponsors and support

Primary sponsor: University Medical Center
Source(s) of monetary or material Support: Maastricht university medical center
Stichting Hartsvrienden Rescar

Intervention

Outcome measures

Primary outcome

1. Activation of blood coagulation: Erythrocyte-derived and platelet-derived microparticles (EryMP and PMP) are measured because these are known as important activators of coagulation and inflammation and abundantly present in pericardial blood;

2. Complete blood count: Hematocrit (Ht), red blood cells (RBC), platelets (Plt) and leukocytes

(WBC) are markers for the quality of the salvage product;

3. Hemolysis: Free hemoglobin (freeHb), potassium (K) and lipid content (triglicerides (TGl), free fatty acids(FFA)) are measured as markers of hemolysis (due to active suctioning of the cell saver and air exposure) and washing efficiency;

4. Red blood cell function: 2,3-diphosphoglycerate (2,3-DPG) will be analysed as a crucial biomarker of the RBC oxygen unloading capacity and therefore as a marker of RBC function of salvaged blood in general. Also, adenosine triphosphate (ATP) will be analysed;

5. ROTEM (ROtational ThromboElastoMetry) and CAT (Calibrated Automated Thrombography) parameters to assess patients coagulation profile.

Secondary outcome

1. Peri- and postoperative blood loss (during patients' stay in the ICU);

2. The amount of transfusion products during surgery and during patients' stay in the ICU;

3. A continued temperature peak >38oC after 12 hours in ICU;

4. Intubation time;

5. CRP level.

Study description

Background summary

Pericardial blood during cardiac surgery is highly activated. This blood can be washed with a cell saver device. Unfortunately, fat and leukocyte particles are not adequately removed by cell savers. Fat and leukocytes could have a negative influence on blood coagulation. There are also concerns regarding coagulopathy after autotransfusion because of loss of plasma proteins, platelets and coagulation factors. In this study a reservoir will be used as a cell saver reservoir, because of it's claimed filtration capacity of both leukocytes and lipids, and will be compared with a cell saver reservoir which does not remove leukocytes and lipids. The aim is to investigate the quality of this cell saver blood, and to see whether this affects also the coagulation profile of the patient after autotransfusion by performing thromboelastometry (ROTEM) and Calibrated Automated Thrombography (CAT).

Study objective

We hypothesize that autotransfusion of leukocytes and lipid depleted cell saver blood leads to less prone inflammation and coagulopathy after cardiac surgery. We expect a less

activated (cell derived-microparticle poor) and a more ‘pure’ (hemolysis free, leukocytes and lipid poor) autologous cell washed blood product.

Study design

T0: After induction of anaesthesia in operation room;

T1: Post cross-clamp in operation room;

T2: Post cardiopulmonary bypass in operation room;

T3: Post autotransfusion in the intensive care unit.

Intervention

In total 50 patients will be assigned to the intervention group. In this group a autotransfusion reservoir which removes leukocytes and lipids will be used instead of the reservoir not removing leukocytes and lipids.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female patients selected for CABG or AVR surgery or CABG/AVR surgery;

2. Age between 18 and 85 years.

Exclusion criteria

1. Patients with preoperative coagulation disorders;

2. Patients who used oral anticoagulants, clopidogrel or thrombolytica within the previous 5 days;

3. Patients with renal insufficiency;

4. Patients with hepatic disorders;

5. Patients who use cortico-steroids;

6. Patients with active sepsis/endocarditis;

7. Oncological patients;

8. Emergency patients.

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-04-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion Date:	25-01-2011
Application type:	First submission

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	NL2587
NTR-old	NTR2712
CCMO	NL.34179.068.10 / 10-2-095;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Bosch, Y.P., Y.M. Ganushchak, and D.S. de Jong, Comparison of ACT point-of-care measurements: repeatability and agreement. Perfusion, 2006. 21(1): p. 27-31.