Quality assessment of intraoperative cell salvage and autotransfusion

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Primary objective: to asses the quality of a reservoir which removes leukocytes and lipids combined with the Continuous Autotransfusion System (CATS) regarding the autotransfusion product in general and red blood cell function in particular....

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36719

Source
ToetsingOnline

Brief title
Quality assessment of autotransfusion

Condition

- Other condition

Synonym
Inflammation and infection / coagulopathy and disturbed clotting

Health condition

Inflammatoire reacties en coagulopathie bij hartchirurgische patienten

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Stichting hartsvrienden Rescar

Intervention

Keyword: autotransfusion, coagulopathy, inflammation, quality assessment

Outcome measures

Primary outcome

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.

Complete blood count : hematocrit (Ht), red blood cells (RBC), platelets (Plt) and leukocytes (WBC) are markers for the quality of the salvage product.

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.

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.

ROTEM (ROtational ThromboElastoMetry) and CAT (Calibrated Automated

Thrombography) parameters to assess patients coagulation profile.

Secondary outcome

- peri- and postoperative blood loss (during patients* stay in the ICU)

- the amount of transfusion products during surgery and during patients* stay

in the ICU

- a continued temperature peak >38oC after 12 hours in ICU

- intubation time

- 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

Primary objective: to asses the quality of a reservoir which removes leukocytes and lipids combined with the Continuous Autotransfusion System (CATS) regarding the autotransfusion product in general and red blood cell function in particular.
Secondary objective: to asses the coagulation profile of the patient with ROTEM and CAT after autotransfusion by CATS Cell Saver with and without the reservoir

which removes leukocytes and lipids.

Study design

Prospective controlled randomized observational study.

Intervention

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

Study burden and risks

During surgery only 15ml of blood will be collected from the patient, and 40ml of blood will be collected from the cell saver device. The maximum amount will be 65 mL. The maximum amount of blood that will be taken from the patient in the intensive care unit (ICU) is 50 mL (routine analysis). This will not affect the condition of the patient. There will not be any risk associated with participation in this study. The research will not directly be beneficial to the participants. However, it is supposed to be beneficial to all patients who need a cell saver device in the near future.

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

- Male or female patients selected for coronary artery bypass grafting (CABG) or aortic valve replacement (AVR) procedures, or combined CABG/AVR surgery.
- Age between 18 and 85 years.

Exclusion criteria

- Patients with preoperative coagulation disorders
- Patients who use anticoagulant medication
- Patients with renal insufficiency
- Patients with hepatic disorders
- Patients who use cortico-steroids
- Patients with active sepsis/endocarditis
- Oncological patients
- Emergency patients
- Jehovah*s witnesses

Study design

Design

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

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-06-2011
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Autotransfusion reservoir
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-03-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-08-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL34179.068.10