CLINICAL EVALUATION OF THE EFFECTIVENESS OF A LEUCO-LIPID FILTER APPLIED TO INTRA-OPERATIVE CARDIOTOMY SUCTION IN PATIENTS SUBJECTED TO EXTRACORPOREAL CIRCULATION.

No registrations found.

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

Summary

ID

NL-OMON28768

Source
Nationaal Trial Register

Health condition

Three groups of 50 patients, scheduled for myocardial revascularization surgery with the use of cardiopulmonary bypass.

Sponsors and support

Primary sponsor: University Hospital Brussels
Laarbeeklaan 101
1090 Brussel
Source(s) of monetary or material Support: Hartcenter University Hospital Brussels

Intervention

Outcome measures

Primary outcome

Clinical evaluation of a filter for the removal of lipid particles and leukocytes from mediastinal suctioned blood during cardiopulmonary bypass (CPB).

Secondary outcome

1. Does filtration of the lipid particles reduce the inflammatory response to CPB?

2. Evaluation of the capacity of removing white blood cells from suction blood by cardiotomy filtration;

3. Research on possible adverse effects that the filter may have on blood rheology (increased haemolysis, drop in platelets, etc.);

4. Does the decrease of inflammatory response and a lower lipid micro emboli level have any clinical impact (in particular, the myocardial, pulmonary, renal and neurological functions are to be evaluated)?

Study description

Background summary

During cardiac surgery blood loss from the intra-thoracic cavity is collected in a separate reservoir. After a clinical consideration based on the quantity of blood loss and the patient fluid balance, the blood collected in the separate suction reservoir is either returned in the circulation or discarded. The reinfusion of the collected blood can be done either through the study reservoir (leuco-lipid) or through the standard reservoir (control group).

Study objective

1. Does filtration of the lipid particles reduce the inflammatory response to CPB?

2. Evaluation of the capacity of removing white blood cells from suction blood by cardiotomy filtration;

3. Research on possible adverse effects that the filter may have on blood rheology (increased haemolysis, drop in platelets, etc.);

4. Does the decrease of inflammatory response and a lower lipid micro emboli level have any clinical impact (in particular, the myocardial, pulmonary, renal and neurological functions are

to be evaluated)?

Study design

Evaluation of micro emboli counts:

1. Emboli quantifier, EDAC.

Evaluation of lipid removal:

1. Triglycerides*;

2. Total Cholesterol*.

Evaluation of myocardial function:

1. Enzymes* (CK, CK-MB, LDH, Troponine T);

2. SvO2*;

3. Post operative use of inotropes or vasoconstrictors;

4. Arrythmia.

Evaluation of pulmonary function:

1. Time to extubation;

2. Prolonged intubation (>24 hours);

3. Postoperative PaO2/FiO2;

4. Reïntubation.

Evaluation of renal function:

1. Fluid balance;

2. Urea level* (mg/dl);

3. Creatinin level* (mg/dl);

4. Creatinin clearance* (ml/kg/min);

5. Urinary MA/cr**;

6. Diuresis.

Evaluation of the neurological function:

1. Incidence of any neurological complications.

Evaluation of hematological disturbances:

1. Haematocrit and hemoglobin*;

2. Platelet count*;

3. Fibrinogen*;

4. Requirement for transfusion (ml/component);

5. Reintervention for bleeding.

Evaluation of the inflammatory response and biocompatibility:

1. White blood cell count*;

2. Leukocyte formula*;

3. C3a**;

4. CRP*;

5. Neutrophil elastase.

Other parameters:

1. Hours of ICU stay;

2. Days of hospitalization;

3. Morbidity;

4. Mortality.

Time of evaluation:

* Pre-operative, admission on ICU, Evening ICU, POD1, POD2, POD3, POD4. (n7);

** Pre-operative, admission on ICU, POD1, POD4. (n4).

Intervention

During Cardiopulmonary bypass, shed blood is stored in a seperate suction device. If the stored blood is clinically important, it needs to be added to the circulation. A clinical evaluation of a filter is to be evaluated. We compare 3 groups:

1. A leucolipid filtered group;

2. A standard filtered group;

3. A group where the blood is of no clinical importance, so it can be wasted.

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Eligibility criteria

Inclusion criteria

All patients admitted for coronary artery bypass grafting surgery. A clinical consideration will be taken over the patient’s blood loss. If blood loss is low, it will be discarded. If blood loss is significant for patients blood balance, the volume will be added to the circulation. The filter used for filtration will contain a leuco-lipid filter or contain a standard filter.

Exclusion criteria

1. Repeated surgery;

2. Requirement for dialysis;

3. Urgencies;

4. Emergencies;

5. Previous major cerebro-vascular insults;

6. The use of intra aortic balloon pump.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-01-2011

Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion Date:	13-01-2011
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	NL2571
NTR-old	NTR2696
Other	MEC UZ Brussel : 2010/258
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A