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

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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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28768

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: University Hospital Brussels
Laarbeeklaan 101
1090 Brussel
Overige ondersteuning: Hartcenter University Hospital Brussels

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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)?

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-01-2011
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2571
NTR-old	NTR2696
Ander register	MEC UZ Brussel : 2010/258
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A