Quality assessment of cell saved blood.

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

Samenvatting

ID

NL-OMON23212

Bron
NTR

Verkorte titel
Quality assessment of autotransfusion

Aandoening

- coagulopathy
- inflammation

Ondersteuning

Primaire sponsor: University Medical Center
Overige ondersteuning: Maastricht university medical center
Stichting Hartsvrienden Rescar

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Age between 18 and 85 years.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-01-2011
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	NL2587
NTR-old	NTR2712
CCMO	NL.34179.068.10 / 10-2-095;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
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.