Do washed irradiated red blood cells with a balanced solution improve the quality of the priming in cardiopulmonary bypass for neonates and infants?

Published: 26-10-2009
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Improve the quality of red blood cells used for cardiopulmonary bypass for neonates and infants with a bodyweight smaller then 10 Kg.

Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON32940

Source
ToetsingOnline

Brief title
Washing red donor bloodcells for CPB (Cardio Pulmonary Bypass)

Condition

- Cardiac therapeutic procedures

Synonym
Quality of red bloodcells

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CPB, neonates, priming, red blood cells

Outcome measures

Primary outcome

Hemoglobin, hematocrit, platelet count, potassium, sodium, chlorine, lactate,

free hemoglobin and blood gasses will be measured by standard protocol.

Secondary outcome

Ventricular function assessment will be measured by routine intra-operative

Tran esophageal echocardiography and by thermo dilution. Hospitalization and

ventilation period will be noted.

Study description

Background summary

Every unit of irradiated red blood cells contents an increased level of lactate and potassium. The concentration is depended of the storage time.
It is possible to wash irradiated red blood cells before using it. The result is a unit of red blood cells without lactate and potassium in a pH neutral solution

Study objective

Improve the quality of red blood cells used for cardiopulmonary bypass for neonates and infants with a bodyweight smaller then 10 Kg.

Study design

Patients with a body weight smaller then 20 Kg will be randomly allocated in one of two groups: unwashed red blood cells and pre-washed red blood cells by using the method of randomly permuted blocks of 10.

Intervention

Donor red blood cells (pre-washed group) will be washed by a cellsaver before using it in the prime of the cardiopulmonary bypass circuit.

Study burden and risks

Washing red blood cells is not related with extra risk for patient treatment it supposed to be an improvement of quality.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Neonates and infants with a bodyweight of < 20 kg
Elective heartsurgery

Exclusion criteria

Hepatic insufficienty
Renal insufficiency
Procedures with deep hypothermic circulatory arrest
Procedures with a prolonged low flow technique
Infants with a body weight > =20 kg
Emergency procedures

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Not approved

Date:	26-10-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL29013.000.09