Regulation of colloid osmotic pressure during cardiopulmonary bypass in infants: prospective randomised trial.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON32152

Source
ToetsingOnline

Brief title
COP regulation during CPB in Infants

Condition

- Congenital cardiac disorders

Synonym
regulation of COP during CPB

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: COP, CPB, Infants, Regulation

Outcome measures

Primary outcome

Patients will be weighted immediately preoperatively and postoperatively before leaving the OR. At the same moments extravascular lung water (EVLWI) will be measured with the PiCCO monitor.

Ratio between the fraction of inspired oxygen and the partial pressure of oxygen in arterial blood (PaO2/FiO2) and positive end - expiratory pressure (PEEP) will be recorded preoperatively, before leaving the OR, at 4 and 24 hour postoperatively. Hemoglobin concentration (Hb), Hematocrit (Hct) and platelet count (Pl), COP and serum albumin concentration (Alb) will be measured preoperatively and before leaving the OR, during the CPB at the 5 minutes on bypass and at the end. During the postoperative period, measurements will be performed at 4 and 24 hours in the ICU.

Secondary outcome

CPB data such as; CPB time, aortic cross-clamp time, lowest nasopharyngeal temperature, and surgery data, length of stay at the ICU and duration of mechanical ventilation will be collected during the study period. Type and volume of all crystalloid, colloid and blood components administrated in the OR, including transfusion during the CPB, and administrated during the stay at the ICU will be noted.

Intraoperative and postoperative blood loss and urine output will be recorded,

together with intraoperative and postoperative use of diuretics.

Study description

Background summary

Cardiopulmonary bypass (CPB) utilized in cardiac surgery remains a nonphysiological procedure that may cause severe hemodilution and an acute inflammatory body response. Therefore, capillary leakage syndrome (CLS), a condition of episodic capillary hyperpermaebility to macromolecules, that shifts fluid and plasma proteins from the intravascular to the interstitial space, may occur. Variety of colloidal and crystalloid solutions used in the prime of a CPB circuit and during CPB very often decrease level of serum COP. Lower plasma COP favours a fluid shift from the intravascular space into interstitial space, with formation of organs edema.

Study objective

The primary goal of this study is to compare the routinely use infant COP protocol (old protocol) with new approach to the COP regulation (new protocol) with regard to perioperative fluid shift, lung function and allogeneic transfusion requirements.
Diminishing of fluid shift into the extravascular space will result in higher levels of hematocrit and platelet count in the postoperative period. Therefore, transfusion of allogeneic blood products will be reduced. The impairment of pulmonary function following CPB will be attenuated and the recovery and the length of ICU stay will be shorter.

Study design

Prospective randomized trial with two groups of patients with body weight under 10 kg . For both study groups, CPB prime (300 ml) will contain homologous red blood cells concentrate (RBCs), fresh-frozen plasma (FFP) and Gelofusine (B.Braun, Melsungen, Germany). The amount of RBCs added to the prime will be calculated to achieve a hematocrit of 0.28 L/L during CPB and ratio between volume of FFP and Gelofusine will be 1:1.
In the old protocol group a 0.5 g/kg BW of human albumin (20% solution) will be added into the prime, in accordance with existing infant CPB protocol. In the new protocol group, volume of human albumin (20% solution) will be calculated to achieve 5% albumin concentration in the CPB prime.
Regulation of COP during the CPB will be achieved by addition of human albumin 20% solution. In the old protocol group during the CPB target value of COP will be not lower than 15 mmHg and in the new protocol group COP not lower than 18

mmHg.

Intervention

In the old protocol group a 0.5 g/kg BW of human albumin (20% solution) will be added into the prime, in accordance with existing infant CPB protocol. In the new protocol group, volume of human albumin (20% solution) will be calculated to achieve 5% albumin concentration in the CPB prime. Regulation of COP during the CPB will be achieved by addition of human albumin 20% solution. In the old protocol group during the CPB target value of COP will be not lower than 15 mmHg and in the new protocol group COP not lower than 18 mmHg.
Surgical and anaesthesia procedures will be not altered for the purpose of this study.

Study burden and risks

NA

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants with body weight lower or equal to 10 kg, elective operation

Exclusion criteria

Infants with body weight of more than 10 kg.
Reoperations
Urgent operations
Premature
Infants with kidney and or liver insufficiency

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2008
Enrollment:	120
Type:	Actual

Medical products/devices used

Product type:	Medicine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	28-02-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-04-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2008-000069-41-NL
CCMO	NL21403.078.08