Regulation of COP during CPB in infants

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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).

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

Samenvatting

ID

NL-OMON27927

Bron
NTR

Verkorte titel
N/A

Aandoening

COP CPB infants prime regulation heartsurgery

Ondersteuning

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Overige ondersteuning: NA

fund= initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Study primary endpoints variables are:
- Intravascular COP
- Plasma albumin concentration
- Body weight gain measured at the end of the operation, before leaving the operation room.

We expect 50 % increase of COP and albumin levels by implementation of the new protocol. The body weight gain is expected to be diminished by 75%.
Additionally, we would like to study the relationship between the COP value at the end of the operation and postoperative transfusion requirements and blood loss, gas exchange, duration of mechanical ventilation and length of stay in the intensive care unit (ICU).

Toelichting onderzoek

Achtergrond van het onderzoek

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

Short summary

1. Background.

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.
This prospective study is design to determine whether a new composition of CPB prime and higher target value of COP during the CPB beneficially effects perioperative COP level, plasma albumin level, hematocrit, platelets plasma concentration, extravascular lung water and body weight gain. Additionally, we would like to study the relationship between the perioperative COP values and fluid management, gas exchange, ventilatory parameters, duration of mechanical ventilation and length of stay in the intensive care unit (ICU).

2. Study goals

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.

3. 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.

4. Study population.

All consecutive 120 patients with body weight less than 10 kg undergoing elective first time cardiac surgery in our institution will be eligible to take part in the study. Infants with associated noncardiac conditions such as hepatic of renal insufficiency and pramaturity will be excluded as well as the procedures that required deep hypothermic circulatory arrest.

5.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.

6. Primary variables

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.

7. Secondary variables

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.

Doel van het onderzoek

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).

Onderzoeksopzet

A 24 months study period is required to obtain sufficient data from the study population of 120 patients (an average number of infants less than 10 kg who underwent cardiac surgery in our institution is 81 per year). The study would start directly when the approval from the METC is obtained.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Infants with body weight < 10kg

2. Elective surgery

3. First time surgery

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Infants with body weight >= 10 kg

2. Prematurity

3. Reoperation

4. Non elective surgery

5. Hepatic and or renal insufficiency

6. Procedures that require deep hypothermic circulation arest

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-04-2008
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-10-2008
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	NL1419
NTR-old	NTR1479
Ander register	MEC 2008-037 : THCHOZ-2008-01
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
Publications
- Effects of cardiopulmonary bypass circuit reduction and residual volume salvage on allogeneic transfusion requirements in infants undergoing cardiac surgery. Hanna D. Golab, Johanna J.M. Takkenberg, Gerri L. van Gerner-Weelink, Marianne J. Wijers, Thierry V. Scohy, Peter L. de Jong, and Ad J.J.C. Bogers. Interactive CardioVascular and Thoracic Surgery 2007; 6:335-339

- “Processing and transfusion of residual cardiopulmonary bypass volume: effects on haemostasis, complement activation, postoperative blood loss and transfusion volume”, CR. Daane, HD Golab, MJ Wijers, AJJC Bogers. Perfusion, 18(2):115-21, 2003 April

- “The effect of temperature management during cardiopulmonary bypass on clinical outcome in pediatric patients undergoing correction of ventricular septal defect”. HD Golab,

MJ Wijers, M. Witsenburg, G. Bol-Raap, E.Cruz, AJJC. Bogers.The Journal of Extra-Corporeal Technology, Volume 32, Nr.2, June 2000

- “Clinical experience in the Low-Flow perfusion technique for neonates” HD Golab, E Bos, J Quaegebeur, J Hess, MJ Wijers. Proceedings of 4th European Congress on Extra-Corporeal Circulation Technology, Noordwijk June 1991

- “Clinical comparision on arterial line filters Bentley 1025C and Swank HF 6000 used during CPB for CABG operations”. HD Golab. NeSECC Journaal, Juni 1990

Presentations
- “Isolated Limb perfusion in Rotterdam 1973 – 2002”11th international symposium AmSECT, Aruba, 2002

- “Rotterdam experience with ILP”. 21st Annual Meeting SCANSECT, Oslo, 2001

- “The effects of CPB temperature on clinical outcome after heart surgery” Wetenschappelijke Bijeenkomst NeSECC, Nieuwer ter Aa, 2000

- “Influence of CPB temperature on clinical outcome in pediatric patients undergoing correction of VSD’8th European Congress on ECC, Vouliagmeni, Greece,1999

- “Clinical experience in the Low-Flow perfusion technique for neonates”4th European Congress On ECC, Noordwijk, 1999

