Restrictive red blood cell policy in postoperative cardiac surgery patients.

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Reduction in red blood cell transfusions is associated with a reduction morbidity, expressed as ventilator days, length of PICU and hospital stay, nosocomial infections.

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

Samenvatting

ID

NL-OMON24780

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

pediatric postoperative cardiac surgery patients, red blood cell transfusion, morbidity, nososcomial infection, MBL, venous saturation
pediatrische postoperatieve cardiochirurgische patienten, erytrocytentransfusie, morbiditeit, nosocomiale infecties, MBL, veneuze saturatie

Ondersteuning

Primaire sponsor: D.A.H. de Gast-Bakker, kinderarts-intensivist, LUMC
IC centrum, LUMC, Prof. Dr. L.P.H.J. Aarts
Sanquin bloedbank zuid-west Nederland (Dr.L.M.G. van de Watering)
Overige ondersteuning: IC centrum, LUMC, Prof. Dr. L.P.H.J. Aarts
Sanquin bloedbank zuid-west Nederland, Dr.L.M.G. van de Watering

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduction in red blood cell transfusion and the morbidity related to the transfusion (expressed as ventilator days, length of PICU and hospital stay, nosocomial infections).

Toelichting onderzoek

Achtergrond van het onderzoek

The practise of red blood cell transfusion in critically ill children is common practise. Treatment of anemia is the mean rationale for transfusing children after cardiac surgery. It is generally beleived that thay have a lower margin of safety for tolerance of low hemoglobin and that oxygen consumption improves when they are transfused. However this concept has never been proven. Additionally a well defined threshold value when to transfuse is unavailable. Recents studies in adults and children show increasing morbidity related to transfusion requirements. No adverse outcome was observed in a recent study in stable critically children when restricting the transfusion policy, accepting a lower threshold seems appropriate. Continuous oxygen saturation monitoring may be helpfull in the decision making of whether a red blood cell transfusion is required.

Doel van het onderzoek

Reduction in red blood cell transfusions is associated with a reduction morbidity, expressed as ventilator days, length of PICU and hospital stay, nosocomial infections.

Onderzoeksopzet

The study starts at the operating room and patients are follwed for 28 days.
Continuous venous saturation measurement is maximum 72 hours, cerebral oxygen saturation (NIRS) 24 hours, all other monitoring is according to the standard protocol.
Bloodsamples are according to the standard protocol with two additional samples (after induction at te OR, after admittance on PICU).

Onderzoeksproduct en/of interventie

After inclusion the patients are randomised in two groups (restrictive and liberal transfusion policy). The transfusion triggerpoint for the restrice group is set at a hemoglobin of 5 mmol/L versus 6,8 in the liberal group.
In both groups patients are treated according to the standard protocol with all the minitoring they require postoperatively. Additionally continuous venous saturation is measured during maximum 72 hours, the storage time of the red blood cell is registered and mannose binding

lectine is measured twice.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Pediatric patients with a non-cyanotic congenital heart defect (>3 kg, >6 weeks and < 6 years) undergoing cardiac surgery.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Neonates;

2. Underlying hematological disease (hemoglobinopathy);

3. Patients participating in another study that may interfere with this study.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-03-2009
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-03-2009
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	NL1608
NTR-old	NTR1691
Ander register	METC LUMC : P07-168
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A