Premature Umbilical Cord Blood (PUCB).

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Can allogeneic red cell transfusions for preterm/very low birth weight newborns be reduced and is this associated with favourable outcome of usual neonatal complications (infections, cerebral bleeding , duration of assisted ventilation and death)...

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

Samenvatting

ID

NL-OMON27961

Bron
NTR

Verkorte titel
PUCB

Aandoening

The study population exists of prematures born after a gastational age of less than 32 weeks and 32-36 weeks with Apgar score <6, for whom at least 1 erythrocyte product is stored. The NICU is informed that this patient is a study candidate. The transfusion indications are decided by the treating physicians according to quidelines from the Dutch Society for Neonatology. In case the first transfusion is indicated the patient is randomly assigned to the autologous or an allogeneic red cell product. A pre and post transfusion Hb is determined. In case more transfusions are needed the patient who was assigned to the autologous transfusion arm receives autologous red cells as long as products are available or up to a period of 3 weeks.

Ondersteuning

Primaire sponsor: Project 945-04-609 of ZonM/w
Project OOPEP/1044 of Sanquin Blood supply
Overige ondersteuning: ZonM/w
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Proportion of patients who received allogeneic transfusions and the total volume of administered allogeneic red cells.
Days of support of vital functions in the NICU.

Toelichting onderzoek

Achtergrond van het onderzoek

Bloodsubstitutes are becoming a pivotal medical aim. Efforts to find blood substitutes instead of donor blood are enforced by the awareness that allogeneic blood transfusions, despite optimal safety precautions, can be associated with worse clinical outcome. In addition there is a realistic expectation of decrease in the numbers of safe blood donors in the near future. Preterm newborns with a gestational age less than 32 weeks and/or 32-36 weeks and Apgar score <6 have a high probability to receive blood transfusions. Preterm newborns also have a high risk for respiratory and other organ failure, septicaemia and cerebral bleeding. In adults, blood transfusions are associated with increased morbidity and mortality. It is conceivable that preterm infants are even more susceptible to the adverse effects of allogeneic transfusions. Neonatal diseases may have life-long sequelae such as chronic lung disease, impaired neurodevelopmental outcome and retinipathy.

- Cordblood (CB) is generally discarded, but contains red cells, immature hematopoietic cells and stem cells suitable for autologous and allogeneic usage. CB red cells can be harvested, stored and transfused without side effects.
In the proposed double-blind randomised study we compare the use of autologous CB red cells with allogeneic transfusions.
- Primary outcome measure is a meaningfull (> 50% reduction) in allogeneic red cell transfusions.
- Secondary parameters are
a. postnatal complication rate (infections, duration of respiratory assistance, intracranial bleeding ,length of ICU-stay)
b. feasibility to obtain autologous CB transfusions on a wide scale
c. costs compared to standard treatment.

Doel van het onderzoek

Can allogeneic red cell transfusions for preterm/very low birth weight newborns be reduced and is this associated with favourable outcome of usual neonatal complications (infections, cerebral bleeding , duration of assisted ventilation and death) resulting in shortening of the need of vital support necessitating NICU care.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Transfusion of autologous red cord blood cell concentrate vs. transfusion of stored allogeneic red blood cell concentrates.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. Pregnant women;

2. Premature (gestational age of < 36 weeks) who require a red blood cell transfusion.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Hemolytic disease of the newborn;

2. Maternal infections such as HIV/HCV/HBV/CMV/ Toxoplasma/ Treponema pallidum or maternal septicaemia;

3. Ruptured membranes >24 hr and body temp. >38 gr. C;

4. placenta praevia, version, solutio placentae;

5. antibiotics/fungostatica < 48 hr prior to partus.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2004
Aantal proefpersonen:	600
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	07-09-2005
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	NL219
NTR-old	NTR256
Ander register	: N/A
ISRCTN	ISRCTN01566504

Resultaten

Samenvatting resultaten
N/A