Premature Umbilical Cord Blood (PUCB).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27961

Source
NTR

Brief title
PUCB

Health condition

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.

Sponsors and support

Primary sponsor: Project 945-04-609 of ZonM/w
Project OOPEP/1044 of Sanquin Blood supply
Source(s) of monetary or material Support: ZonM/w
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Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Days of assisted ventilation support;

2. Cumulative complication incidence
(infections, cerebral events);

3. Length of hospital stay;

4. Mortality;

5. Feasibility of erythrocyte collection from cord blood;

6. Costs of transfusions;

7. Costs of care;

8. 2 year and 5 years neurodevelopmental follow-up.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

1. Pregnant women;

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2004
Enrollment:	600
Type:	Actual

Ethics review

Positive opinion

Date:	07-09-2005
Application type:	First submission

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
NTR-new	NL219
NTR-old	NTR256
Other	: N/A
ISRCTN	ISRCTN01566504

Study results

Summary results

N/A