

Premature Umbilical Cord Blood (PUCB)

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 14/11/2008	Condition category Pregnancy and Childbirth	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

NTR256

Study information

Scientific Title

The use of autologous cord blood for anaemia of prematurity

Acronym

PUCB

Study objectives

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 Neonatal Intensive Care Unit (NICU) care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised, double-blind, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anaemia of prematurity

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

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. Two-year and five-year neurodevelopmental follow-up

Completion date

01/12/2007

Eligibility

Key inclusion criteria

1. Pregnant women
2. Premature (gestational age of less than 36 weeks) who require a red blood cell transfusion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Haemolytic disease of the newborn
2. Maternal infections such as human immunodeficiency virus (HIV)/hepatitis C virus (HCV)/hepatitis B virus (HBV)/cytomegalovirus (CMV)/Toxoplasma/Treponema pallidum or maternal septicemia
3. Ruptured membranes greater than 24 hours and body temp greater than 38°C
4. Placenta praevia, version, solutio placentae
5. Antibiotics/fungostatica less than 48 hours prior to partus

Date of first enrolment

01/12/2004

Date of final enrolment

01/12/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Centre (LUMC)

Leiden

Netherlands

2301 CD

Sponsor information

Organisation

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Funder Name

Sanquin Bloodbank Amsterdam (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration