ISRCTN01566504 https://doi.org/10.1186/ISRCTN01566504

# Premature Umbilical Cord Blood (PUCB)

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof A. Brand

**Contact details**
Leiden University Medical Centre (LUMC)
P.O. Box 2184
Leiden
Netherlands
2301 CD
+31 (0)71 568 5053
Anneke.Brand@bloodrtd.nl

## 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 septicaemia
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