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Premature Umbilical Cord Blood (PUCB)

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
01/12/2004

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

Age group
Adult

Sex
Female

Target number of participants
600

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)

Sponsor details
P.O. Box 93245
Den Haag
Netherlands
2509 AE
+31 (0)70 349 5111
info@zonmw.nl

Sponsor type
Research organisation

Website
http://www.zonmw.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration