:Improve the outcome of Preterm born neonates by Cord Blood Transfusions

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Primary objective: To assess the feasibility of donor screening, collection, production and storage of sufficient CB-RBC products to potentially meet the transfusion need in extremely preterm neonates.

Ethical review	Approved WMO
Status	Pending
Health condition type	Red blood cell disorders
Study type	Observational invasive

Summary

ID

NL-OMON57429

Source
ToetsingOnline

Brief title
Pre-Cord

Condition

- Red blood cell disorders

Synonym
Anemia of the premature, red blood cell shortage

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cord blood, Extremely preterm neonates, Red blood cell product

Outcome measures

Primary outcome

The primary endpoint is the number of CB-RBC products produced from CB donations that meet the quality requirements and release specifications according to the Dutch Guideline for Blood Products. In order to correlate the number of collected CB-RBCs to the neonatal transfusion need, the number of RBC transfusions required for neonates admitted to the EMC and LUMC Neonatal Intensive Care Unit (NICU) will be recorded as well.

Secondary outcome

Not applicable

Study description

Background summary

Anemia occurs in almost all extremely preterm neonates born before 28 weeks of gestation age (GA) and in neonates with extremely low birth weight <1000 gram. These neonates receive on average of 2-4 red blood cell concentrate (RBC) transfusions (1). Currently, RBCs are derived from blood, donated by adults. This contains adult hemoglobin (HbA), whereas neonates have a predominance of fetal hemoglobin (HbF). As a result, transfusion of adult-RBCs leads to a marked decrease in HbF-levels in preterm neonates (2). As HbA has a different oxygen-dissociation curve this negatively impacts the premature vascular environment and still-developing organs by an increase in oxygen release leading to inflammation and oxidative stress. In recent studies both RBC transfusions as well as a steep decline in HbF levels are associated with increased morbidity due to a higher incidence of prematurity-associated diseases affecting eyes, lungs and gut (1, 4, 5). In order to prevent the transfusion-provoked HbF decline, adult-RBCs should be replaced by transfusions that are processed from a fetal or neonatal donor source, such as placenta or cord blood (CB) from healthy, term neonates. A reservoir of blood that is

usually discarded. This new blood product must meet the European blood bank standards as well as Dutch law and regulations. Therefore the Erasmus Medical Center (EMC) and Leiden University Medical Center (LUMC) have cooperated with Sanquin Blood Supply Foundation (Sanquin) since 2022 to develop a CB-derived red blood cell concentrate transfusion product (CB-RBC) containing HbF, which meets the standards to be transfused. In order to produce enough CB-RBC product, the entire supply chain must function, including donor screening, collection, production and storage.

Study objective

Primary objective: To assess the feasibility of donor screening, collection, production and storage of sufficient CB-RBC products to potentially meet the transfusion need in extremely preterm neonates.

Study design

Prospective multicenter cohort study in the EMC, LUMC and Maasstad Hospital.
Intervention:
1. Collection of residual CB of healthy, term neonates after the delivery of the neonate and after delayed cord clamping is performed.
2. Collection of 10 mL blood in EDTA from the mother during hospital admission for labour by venipuncture to perform donor screening according to guidelines.

Study burden and risks

Minimal burden, a single blood draw of 10 ml, collected in EDTA, from mother is taken during admission by venipuncture (prior to delivery). Collection burden of CB does not exist as CB is residual material.
The general common risks of venipuncture are apprehension, pain, discomfort, extravasation of blood into the tissue causing a bruising or haematoma, and presyncope, including pallor, light headedness, dizziness, nausea, diaphoresis. Other less common and rare side effects are fainting, nerve irritation, infection, arterial puncture, allergy (skin), neuropathic pain, phlebitis, and deep vein thrombosis. Added discomfort associated with participation is unlikely as there are no further interventions in routine care. There is no direct benefit to the study participant. Real benefits are altruistic in nature: participants joining in this study will assist in gathering important information for safety and performance of CB for the collection, processing and storage of CB-RBC products.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: pregnant women admitted to the department of obstetrics in participating hospitals with a healthy term neonate, defined as a GA >=37 weeks can be screened for donation in one of the participating hospitals: EMC, LUMC and Maasstad Hospital. Donation criteria are based on the regular blood donor selection criteria for whole blood donation (Dutch Guideline for Donor Criteria: Richtlijn Donorkeuring, Sanquin). Additional criteria have been made by a working party of our consortium, taking the particular situation into account involving both the pregnant woman as donor and the preterm recipient. Additional standards are formulated for screening for blood-borne infectious diseases and bacterial contamination as well as medication use that can cross the placentas barrier. Informed consent and donor screening is performed in the weeks leading up to birth by midwives, gynaecologists, research nurses and researchers at the obstetrics department. Transfusion requirements will be monitored of all extremely preterm neonates admitted to EMC and LUMC NICU of which the parents have given consent for use of clinical data for research purposes.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Unable to understand or refusing to sign an informed consent;
• Do not pass donation criteria.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	116
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	17-04-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL88831.078.25