Preterm Oxygenation of the Cerebrum: Key for Erythrocyte-transfusion Threshold

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22948

Source
Nationaal Trial Register

Brief title
POCKET

Health condition

Preterm infants, Anemia, Red blood cell transfusion, Transfusion threshold, Neurodevelopmental outcome

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be the neurological outcome at the age of three months post term, based on the motor optimality score (MOS) of the quality of General Movements

(GMs).

Secondary outcome

Secondary outcomes will be the incidence of in-hospital mortality and morbidities NEC, BPD, ROP, and deterioration of IVH assessed at 3 months post term age. Urinary I-FABP levels will be measured to determine intestinal cell damage as early marker for NEC. Cerebral regional tissue oxygen saturation and the total amount of RBC transfusions during the study period of 4 weeks will be recorded.

Study description

Background summary

Neonatal anemia is common in preterm infants. During their stay in the neonatal intensive care unit, most of these high-risk infants receive at least one red blood cell (RBC) transfusion. The lack of knowledge on the balance of potential benefits and risk of RBC transfusion for anemic preterm infants, have led to controversies about the optimal threshold for RBC transfusion for this population.

We intend to conduct a randomized controlled trial, comparing two treatment strategies for RBC transfusion in preterm infants: We will compare a newly developed strategy for treatment of preterm anemia with the current treatment strategy. In the new strategy, transfusion Hb thresholds will be lower by 1 mmol/l compared to the current thresholds, provided adequate cerebral oxygen saturation values are met.

Study objective

Our primary objective is to test our hypothesis that a newly developed strategy with lower Hb thresholds for RBC transfusion than the current ones, provided adequate cerebral oxygen saturation values are met, will lead to a better neurological outcome in preterm infants at three monts post-term.

Study design

The duration of the study will be from signed informed consent (after admission to the NICU) until three months post-term. The intervention period at the NICU will be for a maximum of four weeks. During the study period the infants will have several non-invasive measurements.

Intervention

The intervention strategy group will not receive an RBC transfusion (15-20 ml/kg leukocyte-

reduced erythrocytes) in case of an Hb threshold which is 1.0 mmol/l lower than current guidelines, i.e. at an Hb threshold of 7.0 mmol/L or 6.0 mmol/L depending on ventilatory support, unless cerebral regional tissue oxygen saturation is lower than 72% for at least 30 consecutive minutes during the first four weeks after birth, or until discharge. The control group will be treated according to the current strategy, following the current clinical NICU guidelines with the threshold for RBC transfusion: Hb < 8.0 mmol/L if the infant is ventilated, and Hb < 7.0 mmol/L if not.

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- A gestational age < 32 weeks

- Age between 0 and 7 days

- Written informed consent by legal representative(s)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Chromosomal abnormality (e.g. trisomy 13, 18, 21)

- Perinatal asphyxia resulting in Apgar score (AS) < 5 at five minutes postpartum

- Major congenital malformations that increase the risk of death or adverse neurodevelopmental outcome (congenital cerebral malformations, congenital heart diseases excluding patent ductus arteriosus)

- Diagnosis of NEC prior to inclusion

- Intraventricular and periventricular hemorrhage > grade 2 according to Papile, prior to inclusion

- Alloimmune hemolytic disease, sickle-cell disease or thalassemia

- Any received RBC transfusions prior to inclusion

- Inability to understand Dutch by the parents

- Parents expressing strong philosophical or religious objections to transfusion

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-07-2018
Enrollment:	194
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 45656
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6099
NTR-old	NTR6246
CCMO	NL60383.042.17
OMON	NL-OMON45656

Study results