Study on Transfusion Effects in Preterm infants

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29247

Source
Nationaal Trial Register

Brief title
STEP

Health condition

Preterm neonates, Anemia, Erytrhocytes/Red blood cells, Erythropoietin

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be epo regulation and expression at various ages: baseline epo concentration in umbilical cord blood, epo concentration in blood at the age of two weeks after birth, the degree of DNA methylation in intestinal cells isolated from feces at the age of two weeks after birth, and the degree of DNA methylation in intestinal cells isolated from feces at the age of three to six months post-term. Additionally, if one of the

included infants developed NEC and needs surgery, then a small part of the removed intestine will be analysed in laboratory for intestinal epo gene expression, comparing it with an healthy part which is already available in the laboratory.

Furthermore, we will use Hb levels assessed during standard care and collect information (number and volume) regarding RBC transfusions during the first four weeks of life. Cerebral and intestinal oxygen saturation during the first four weeks after birth and urinary isoprostane concentrations, as biomarker for oxidative stress, will also be determined.

Secondary outcome

Secondary outcomes will be cerebral and intestinal rSO2, urinary I-FABP concentration before and after RBC transfusion, and the prevalence of NEC and its grading at 40 weeks postmenstrual age (PMA). Furthermore, we will assess the neurological condition using the assessment of general movements (GMs) before and after the first RBC transfusion, and the neurological outcome at the age of three months post-term, based on the motor optimality score (MOS) of the quality of the GMs.

Study description

Background summary

Neonatal anemia is common in preterm infants. Anemia may lead to hypoxia, possibly resulting in cell damage. A red blood cell (RBC) transfusion is an intervention aiming to rapidly improve oxygen transport to vital organs, such as the brain and the gut.

Anemia and RBC transfusions result in low and high organ oxygenation respectively. Both might be harmful, and especially high variation in oxygenation may lead to damage in vulnerable organs, such as the brain and the gut. As erythropoiesis is partly upregulated by hypoxia, there might be an association between these oxygenation values and the expression of erythropoietin (epo), which is the essential growth factor for the production of erythrocytes. Anemia leads to decreased oxygen transport and decreased organ oxygenation, whereas RBC transfusion increases oxygenation. It is unknown whether anemia and/or RBC transfusion are related to the expression of epo in gut cells through these various levels of oxygenation. We will therefore explore whether epo regulation and expression in intestinal cells may be associated with the course of hemoglobin (Hb) levels. Furthermore, we will explore if epo regulation and expression may also be associated with anemia, RBC transfusions, oxidative stress, and organ oxygenation in the neonatal period. Secondary, we will evaluate the clinical consequences and the neurological outcome of the variable oxygenation levels.

Study objective

The objective is to explore whether epo regulation and expression, at the age of two weeks

after birth and three to six months post-term, are associated with the course of Hb levels, anemia, RBC transfusions, oxidative stress, and cerebral and intestinal oxygenation in preterm infants during the early neonatal period.

Study design

The duration of the study will be from informed consent, followed by inclusion (after admission to the NICU) until three to six months post-term. The study period at the NICU will be for a maximum of four weeks. During the study period at the NICU the patients will undergo several non-invasive measurements.

Intervention

None

Contacts

Public
UMCG
E.M.W. Kooi
kinderarts-neonatoloog, afdeling neonatologie
Beatrix Kinderziekenhuis, UMC Groningen
Huispostcode: CA 51
Hanzeplein 1
Postbus 30001
Groningen 9700 RB
The Netherlands
050-3614215
Scientific
UMCG
E.M.W. Kooi
kinderarts-neonatoloog, afdeling neonatologie
Beatrix Kinderziekenhuis, UMC Groningen
Huispostcode: CA 51
Hanzeplein 1
Postbus 30001
Groningen 9700 RB
The Netherlands
050-3614215

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

- Before 7 days of age

- 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)

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

- Diagnosis of NEC 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:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-03-2019
Enrollment:	67
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	17-08-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48979
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6447
NTR-old	NTR6625
CCMO	NL62348.042.17
OMON	NL-OMON48979

Study results