Study on Transfusion Effects in Preterm infants

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29247

Bron
Nationaal Trial Register

Verkorte titel
STEP

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-03-2019
Aantal proefpersonen:	67
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-08-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48979
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten