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

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22948

Bron
Nationaal Trial Register

Verkorte titel
POCKET

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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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

- Age between 0 and 7 days

- 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)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	19-07-2018
Aantal proefpersonen:	194
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45656
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten