Implementation of Predictive Intelligent Control of Oxygenation (PRICO®) on High Flow Nasal Cannula Support in preterm infants.

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The use of automated closed loop oxygen control in infants on infants with high flow nasal canulla (HFNC) support, will lead to higher amount of saturations within target range compared to manual control.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23497

Bron
NTR

Aandoening

Prematurity. BPD.

Ondersteuning

Primaire sponsor: MMC Veldhoven, The Netherlands
Overige ondersteuning: Chiesi Farmaceuticals (unrestricted grant)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Saturations within target range (88-95%)

Hyperoxia (saturations >95%)
Hypoxia (saturations <88%)
Severe hypoxia (saturations <80%)

Toelichting onderzoek

Achtergrond van het onderzoek

In order to avoid hypo- and hyperoxia in preterm infants, oxygen administration is manually controlled by the nurses with use of pulseoximetry. However, with manual control of oxygen administration, oxygen saturations are still 50 time percent above or below the target range. New ventilators are able to automatically adjust oxygen administration guided by pulseoxymetry. Different studies in preterm infants on mechanical ventilation or Continuous Positive Airway Pressure (CPAP), have shown that the use of ventilators with closed loop oxygen administration leads to a significant higher amount of saturations within target range. However, recent ventilators combine the closed-loop technology with High Flow Nasal Cannula (HFNC) support, which resembles CPAP. We aim to study the effect of closed loop oxygenation in preterm infants on HFNC on amount of time spent within saturation target range.

Doel van het onderzoek

The use of automated closed loop oxygen control in infants on infants with high flow nasal canulla (HFNC) support, will lead to higher amount of saturations within target range compared to manual control.

Onderzoeksopzet

After birth (Gestational Age<30 weeks) and with FiO2 >0.25, during NICU admission. After parental consent.

Onderzoeksproduct en/of interventie

In this observational cross-over study we mark two consecutive periods of 24 hours each, in whom oxygen delivery to infant will be controlled by the certified PRICO device or manually by the nurse. The sequence of oxygen control (i.e. manual-FiO2 first or PRICO first) will be determined by randomization, using sequentially numbered opaque sealed envelopes.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Preterm infants born with Gestational Age < 30 weeks.

• On HFNC support according to standard of care protocol see table 1.

• Supplemental oxygen need

• Witten parental consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Major congenital abnormalities

• Hemodynamic instability

• Culture proven sepsis <72 h for enrolment

• Post-hoc: change in respiratory support mode (i.e. Intubation, CPAP)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2017
Aantal proefpersonen:	25
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7375
NTR-old	NTR7583
Ander register	METC Veldhoven : N 17.007

Resultaten