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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23497

Source
NTR

Health condition

Prematurity. BPD.

Sponsors and support

Primary sponsor: MMC Veldhoven, The Netherlands
Source(s) of monetary or material Support: Chiesi Farmaceuticals (unrestricted grant)

Intervention

Outcome measures

Primary outcome

Saturations within target range (88-95%)

Hyperoxia (saturations >95%)

Hypoxia (saturations <88%)

Severe hypoxia (saturations <80%)

Secondary outcome

Manual interventions on FiO2

Bradycardia (number)

Mean FiO2

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public
Máxima Medical Centre Veldhoven, P.O. Box 7777

H. Niemarkt
Veldhoven 5500 MB
The Netherlands
+31 (0)40 8889350
Scientific
Máxima Medical Centre Veldhoven, P.O. Box 7777

H. Niemarkt
Veldhoven 5500 MB
The Netherlands
+31 (0)40 8889350

Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• Major congenital abnormalities

• Hemodynamic instability

• Culture proven sepsis <72 h for enrolment

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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2017
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results