Safety and feasability of Predictive Intelligent Control of Oxygenation (PRICO) on the Neonatal Intensive Care Unit (NICU)

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To test the safety and feasibility of a closed loop controller of the FiO2 based on the measured SpO2 in a NICU setting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Interventional

Summary

ID

NL-OMON47374

Source
ToetsingOnline

Brief title
PRICO on the NICU

Condition

- Neonatal respiratory disorders

Synonym
hyaline membrane disease, respiratory distress syndrome of the newborn, under developed lungs

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: neonatology, oxygen, respiratory support, saturation

Outcome measures

Primary outcome

The main parameter during the study is the time the SpO2 spend within the

target range.

Secondary outcome

Secondary outcomes are the number of hyper and hypoxic events, average maximum

and minimum SpO2 during these events, number of FiO2 adjustments (manual and

automated) and cerebral oxygen saturation.

Study description

Background summary

Supplemental oxygen is given to preterm infants to ensure that they have an adequate arterial saturation (SpO2). Fluctuations in the SpO2 mean that the fraction of inspired oxygen (FiO2) needs to be adjusted, a challenging and time consuming task. During the recovery of a desaturation there is often an overshoot, resulting in a period of hyperoxia. Hyperoxia interferes with vascular development of the lungs and eyes, and there is growing evidence that hyperoxia may be equally damaging to the developing brain.
An observational study conducted on our Neonatal Intensive Care Unit (NICU) has shown that infants on average spend only 54% of the time within the SpO2 limits and 71 adjustments to the FiO2 are made each day.
An automated controller (PRICO) has been developed that adjusts the FiO2 based on the SpO2. A study in a preterm lamb model has shown the effectiveness of this closed loop controller: less periods of desaturation and hyperoxia were demonstrated.

Study objective

To test the safety and feasibility of a closed loop controller of the FiO2

based on the measured SpO2 in a NICU setting.

Study design

Neonates that are included will start with an 8 hour block of manual adjustment of the FiO2. After completion of this block they will be switched to the automated control of the FiO2 for another 8 hours. After that they are switched back for another 8 hours of manual control, which is used to correct for any changes of the state of the neonate during the trial. For each ventilation type (high frequency , invasive and non-invasive) 24 patients will be included.

Intervention

Automated control of the FiO2 based on the measured SpO2 during 8 hours.

Study burden and risks

There is no burden to the patient, and the risk is minimal. The same patient monitoring is used during the study as during routine care. The closed loop algorithm is implemented in to the Acutronic Fabian HFO ventilator, so that no additional equipment is needed at the bedside.
The controller is designed so that it checks the input signals, the validity of the pulse oximetry and the quality of the ventilation. If any of the checked parameters is not within the specified limits the controller will not adjust the FiO2 and give an alarm.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Neonates who require respiratory support and supplemental oxygen therapy

Exclusion criteria

Planned dismissal or transfer to a other hospital within 24 hours

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-08-2016
Enrollment:	72
Type:	Actual

Medical products/devices used

Generic name:	Neonatal ventilator Fabian HFO with PRICO
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-08-2016
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-06-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
CCMO	NL51887.000.16