Optimal target range of closed loop inspired oxygen support in preterm infants

Published: 12-09-2013
Last updated: 22-04-2024

To assess the optimal target range of the automatic FiO2 function by maintaining the same mean, and narrowing the upper and lower limits of the target range.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON38580

Source
ToetsingOnline

Brief title
OPTICLIO study

Condition

- Other condition

Synonym
Neonatal hypoxie and hyperoxia

Health condition

Hypoxie en hyperoxie bij prematuriteit

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: automatic FiO2 function, closed loop inspired oxygen, target ranges saturation

Outcome measures

Primary outcome

The main outcome parameter will be the proportion of time spent within the saturation ranges used in clinical setting, being 86-94%.

Secondary outcome

Secondary outcomes will be the proportion of time being in hypoxia or hyperoxemia, the distribution of SpO2 between the different periods, and the duration of episodes with hypoxia or hyperoxemia.

Study description

Background summary

Both hypoxia and hyperoxia can lead to organ damage in preterm infants. For this reason the transcutaneously measured oxygen saturation (SpO2) is kept within a range between 86% and 95%. Hypoxia is mainly caused by immature or impaired control of breathing (apnea) and/or a compromised lung function. Hypoxia is often treated with supplemental oxygen, which is manually adjusted to keep the SpO2 within the target range. However, due to clinical instability and the limited time nurses have to adjust the amount of oxygen, preterm infants only spent approximately 50% of the time within the SpO2 target range. Recent studies have shown that the automatic fractional inspired oxygen (FiO2) function of the AVEA ventilator is more capable of maintaining preterm infants within preset saturation ranges than manual adjustment. However, it is unknown to what extent narrowing the SpO2 target range during automated control will result in a tighter control of the SpO2.

Study objective

To assess the optimal target range of the automatic FiO2 function by maintaining the same mean, and narrowing the upper and lower limits of the target range.

Study design

Randomized controlled cross-over trial. In order to find the optimal target range of the automatic FiO2 function of the AVEA ventilator, the target ranges will be set at random order to 86-94%, 88-92%, and 89-91%, respectively for 24 hours each.

Study burden and risks

Burden: There is no additional burden for the patient. All infants participating in the study are subjected to routine neonatal intensive care and are already treated with the AVEA ventilator. The CLIO2 function can be switch on and adjusted without disturbing the patient. As part of standard care, cardio-respiratory and oxygenation status will be monitored continuously. This study does not require extra investigations or interventions.

Benefit and risks: Previous studies have shown that using automatic FiO2 function to keep the patient within preset saturation ranges is feasible and safe. This study will evaluate the efficacy of such a tool narrowing those target ranges. Avoiding hyperoxemia and hypoxia by tight control of the saturation ranges could be a potential benefit for the included patients, as there is now a considerable body of evidence showing that both hypoxia and hyperoxemia can damage multiple organ systems in the preterm infant.
There are no additional known risks to the infant other than those experienced routinely by the premature infants who require supplemental oxygen while in the newborn intensive care nursery.
There are specific alarms and user alerts built in the automatic FiO2 function to improve patient safety in addition to the standard alarms of the pulse oximeter. These alarms will alert the routine caregivers of conditions that require assessment and possible intervention.

Group relatedness: Respiratory instability for which supplemental oxygen is required is a complication occurring exclusively in preterm infants. Any intervention aiming to reduce the risk of hyperoxemia or hypoxia therefore needs to be studied in this specific population at risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Born with a gestational age between 24-32 weeks
Birth weight between 0.4 and 2 kg
Recieving NCPAP or NIPPV with supplemental oxygen for more than 18 hours per day

Exclusion criteria

Lack of parenteral informed consent
Congenital malformation
Requiring vasopressors 48 hours before enrollment
Culture proven infection 72 hours before enrollment

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-01-2014
Enrollment:	41
Type:	Actual

Ethics review

Approved WMO Date:	12-09-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-12-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL45598.018.13