Prolonged administration of closed-loop inspired oxygen support in preterm infants
A randomised clinical trial

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To assess the effectiveness of continuous, long term (weeks) use of a closed-loop FiO2 control system in comparison with M-FiO2 control in preterm infants with non-invasive respiratory support.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48688

Source
ToetsingOnline

Brief title
OptiClio 2 study

Condition

- Other condition

Synonym
neonatal hypoxia 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: automated FiO2 function, closed-loop inspired oxygen, oxygen saturation, preterm infant

Outcome measures

Primary outcome

The primary outcome variable will be the proportion of time for both control

settings with SpO2 within the assigned saturation TR (90-95%), measured over a

time period of a month.

Secondary outcome

Secondary outcomes will be the proportion of time being in hypoxemia or

hyperoxemia, distribution of SpO2 between the different settings, and

cumulative amount of oxygen administered over 28 days and at final study day.

Study description

Background summary

Preterm infants often require supplemental oxygen to prevent hypoxemia, a condition that has been associated with organ damage and an increased mortality. However, too much oxygen supplementation resulting in hyperoxemia may lead to systemic oxidative damage and long-term complications such as retinopathy of prematurity (ROP). For these reasons, oxygen saturation is continuously measured in preterm infants with pulse oximetry (SpO2) aiming to keep it within a safe target range (TR) by manually titrating the fraction of inspired oxygen (FiO2). However, studies in preterm infants have shown that SpO2 targeting is a clinical challenge with patients spending only 50% of the time within their SpO2 TR, due to clinical instability and the limited time

nurses have to adjust the amount of oxygen. Newly developed techniques incorporated in the ventilator provide the opportunity of automated FiO2 control (A-FiO2). Only short term studies (days) have investigated the A-FiO2 function and long term effects need to be evaluated. The short term studies indicate that this closed-loop A-FiO2 reduces time outside the TR, decreases number and duration of hypo- and hyperoxemic episodes, and reduces caregivers* workload compared to manual FiO2 control (M-FiO2).

Study objective

To assess the effectiveness of continuous, long term (weeks) use of a closed-loop FiO2 control system in comparison with M-FiO2 control in preterm infants with non-invasive respiratory support.

Study design

Randomised controlled trial.

Intervention

In order to study the effectiveness over a longer period of time of the A-FiO2 function of the ventilator, preterm infants will be set at random to either continuous use of the A-FiO2 function or to continuous use of M-FiO2 control from first week of life till the 28th day of life.

Study burden and risks

Benefit and risks: Previous studies have shown that using A-FiO2 function to keep the patient within preset saturation ranges is feasible and safe. This study will evaluate the efficacy of such a tool over a longer period. 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 A-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 hypoxemia 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

* From day 7 of life after being born with a gestational age under 28 weeks
* Desaturation lower than 86% at least 8 times per day and/or a structural need of supplemental oxygen > 25%
* Written informed parental consent

Exclusion criteria

* Major congenital anomalies
* If the attending physician deems participation in the study is not in the best interest of the infant
* No ventilator with A-FiO2 function available

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-05-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2019
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	NL62589.018.17