International Multicenter Study of Saturation Targeting by Automatic vs. Manual Adjustment of Inspired Oxygen in Neonates

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

Summary

ID

NL-OMON38883

Source
ToetsingOnline

Brief title
CLIO2 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: closed-loop, fraction of inspired oxygen, oxygen saturation

Outcome measures

Primary outcome

Proportion of time with SpO2 within the assigned target range

Secondary outcome

1. Oxygen saturation distribution

2. Fraction of Inspired Oxygen (FiO2)

3. Time with FiO2 at 21%

4. Oxygen saturation variability

5. Assessment of staff effort

6. Adherence to guidelines

7. Extended episodes with oxygen saturation below or above the target range

8. Incidence of episodes and time with oxygen saturation below the target range

9. Incidence of episodes and time with oxygen saturation above the target range

10. Assessment of response to SpO2 signal loss

11. Assessment of overshoot

Study description

Background summary

Hypoxia en hyperoxia are common events in preterm infants and can potentially lead to organ damage. For this reason oxygen saturations are usually targeted between 86-95%. In case of hypoxia, supplemental oxygen is started and manually adjusted to keep the oxygen saturations within the target range. Because of frequent fluctuations in oxygen saturations in preterm infants and the limited time of nursing staff, manual adjustments in oxygen delivery will only result in an oxygen saturation within the target in 50% of the time. Recent studies have shown that this percentage can be improved safely by using automated adjustment of the inspired oxygen via the ventilator. These results need to be confirmed in a larger cohort of babies in different intensive care units, using different oxygen saturation targets.

Study objective

The objective of this multicenter trial is to evaluate the efficacy and safety of the automatic oxygen delivery adjustment function in the AVEA ventilator in maintaining two target ranges of oxygen saturation in neonates receiving non-invasive respiratory support in comparison to manual oxygen delivery adjustment during routine clinical care.

Study design

Cross-over study in preterm infants with a gestational age between 24-32 weeks on non-invasive support (nasal CPAP). Patients will be treated, in random order, with automated oxygen delivery during 24 hours and manually adjusted oxygen delivery during another 24 hours. Patients will be randomized to one of two oxygen targets (89-91% or 91-95%).

Intervention

Automated adjustment of the inspired oxygen during 24 hours

Study burden and risks

There is no anticipated burden or risk for the patients participating in this study. The non-invasive ventilators used, are standard of care and the only adjustment made is the switching on and off of the automated inspired oxygen function. Previous studies have shown no adverse effects but this needs to be confirmed by the present study.

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 and 32 weeks.
- weight at study entry between 0.4 to 4 kilograms.
- receiving invasive mechanical ventilation or non-invasive respiratory support (NCPAP or NIPPV).
- receiving supplemental oxygen at the time of enrollment and for at least 18 hours during the previous 24 hours.
- expected to complete the 48 hour study period in the current form of respiratory support, i.e. invasive mechanical ventilation or non-invasive respiratory support.
- written informed parental consent.

Exclusion criteria

- major congenital anomalies
- arterial hypotension requiring vasopressor therapy within 48 hours prior to enrollment.
- culture proven sepsis within 72 hours prior to enrollment.
- if the attending physician deems participation in the study is not in the best interest of the infant

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-06-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	18-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	05-07-2013
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	NL42860.018.12