A randomized cross-over trial in the effect of automated oxygen control devices on the distribution of oxygen saturation in preterm infants

Published: 18-10-2018
Last updated: 10-01-2025

To compare the effect of two automated oxygen controllers (Oxygenie and CLiO2) on time spent within oxygen target range in preterm infants.

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

Summary

ID

NL-OMON45888

Source
ToetsingOnline

Brief title
Comparing Oxygen Controllers in Preterm InfanTs (COCkPIT))

Condition

- Neonatal respiratory disorders

Synonym
Respiratory distress, ventilation

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Het wordt gefinancierd via een beurs zonder

voorwaarden door de fabrikant SLE,SLE (Croydon, UK)

Intervention

Keyword: Algorithm, Automation, Oxygen, Premature

Outcome measures

Primary outcome

Proportion of time SpO2 spent within set target range (91-95%)

Secondary outcome

Time SpO2 spent above target range (SpO2 > 95%).

Time SpO2 spent below target range (SpO2 < 91%).

Coefficient of variation of SpO2.

Time in hypoxaemic SpO2 ranges (SpO2 85-90%, 80-84%, <80%).

Time in hyperoxaemic SpO2 ranges (SpO2 96-98% and >98%), when receiving supplemental oxygen.

Frequency of episodes of hypoxaemia (SpO2 <85% and <80%) for >30 seconds and >60 seconds.

Frequency of episodes of hyperoxaemia (SpO2 >=97% and >=99% when receiving supplemental oxygen).

Frequency of episodes of bradycardia (HR <100 bpm more than 10 seconds).

Frequency of FiO2 adjustments during automated control, both made by the controller, and by bedside staff as manual over-rides of the automated system.

Average oxygen exposure

Coefficient of variation of FiO2

Effects on nursing workload in relation to FiO2 adjustment (number of manual FiO2 adjustments)

Confidence of the bedside staff in the automated control system

Study description

Background summary

Preterm infants often need respiratory support and supplemental oxygen for a prolonged period of time during their admission in the NICU. While maintaining the oxygen saturation within the narrow target range is important to prevent morbidity, manual oxygen titration can be very challenging. Automatic titration by an automated oxygen controller has been proven to be more effective in this than manual control. However, to date the performance of different oxygen controllers using different algorithms has not been compared. Based on described differences in algorithm and reported effects of two commercially-available oxygen controllers (CLiO2 and Oxygenie) we hypothesize that the Oxygenie controller will lead to a more effective decrease in occurrence of hypoxaemia without increasing the occurrence of hyperoxaemia when compared to CLiO2.

Study objective

To compare the effect of two automated oxygen controllers (Oxygenie and CLiO2) on time spent within oxygen target range in preterm infants.

Study design

Single blinded randomised cross-over study

Intervention

In both groups oxygen will be automatically titrated with the Oxygenie controller and the CLiO2 controller for 25 hours in random sequence. Automated oxygen control is standard care in our unit.

Study burden and risks

There is no additional burden for the patient as using an automated oxygen controller is standard of care.
Considering the very short study period, there is no additional risk or benefit when the previous automated oxygen controller (CLiO2) will be used to control the fraction of inspired oxygen for 24 hours.
Preterm infants often need respiratory support and supplemental oxygen for a prolonged period of time. Oxygen is often titrated in order to maintain the

SpO2 within the small therapeutic range. Both hypoxaemia and hyperoxaemia are associated with morbidity and mortality in this group, and any intervention aiming to reduce the risk 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 between 24 weeks, 0 days and 29 weeks, 6 days of gestation. Receiving invasive mechanical ventilation or non-invasive respiratory support, receiving supplemental oxygen (at least 25%), with written informed parental consent.

Exclusion criteria

Major congenital anomalies, arterial hypotension, if attending physician considers the infant not stable enough for a switch between ventilators.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-02-2019
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Avea respirator with CLiO2 algorithm and SLE6000 respirator with Oxygenie algorithm
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	18-10-2018
Application type:	First submission
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	NL66058.000.18

Study results

Date completed:	13-02-2020
Results posted:	25-06-2021
Actual enrolment:	11

Summary results
Trial ended prematurely

First publication
01-01-1900