Optimising Oxygenation of Preterm infants during Respiratory support by fine-tuning Automatic TItration of Oxygen

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To compare the effect of two target ranges (91%-95% and 92%-96%) while on automated oxygen control on the time spent under the target range in preterm infants.

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

Summary

ID

NL-OMON50861

Source
ToetsingOnline

Brief title
OPeRATIOn

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: Ministerie van OC&W

Intervention

Keyword: Intensive care, Neonatology, Respiratory, Technology

Outcome measures

Primary outcome

To compare the effect of two target ranges (91%-95% and 92%-96%) while on automated oxygen control while using the OxyGenie controller on the frequency of hypoxic episodes (SpO2 <80% for 1 second or longer).

Secondary outcome

- To compare the effect of two target ranges (91%-95% and 92%-96%) while on automated oxygen control by using the OxyGenie controller on parameters of oxygenation:

a) Distribution of oxygen saturation (the SpO2 histogram).

b) Proportion of time in hypoxaemia and hyperoxaemia (varying degrees).

c) Frequency and duration of hypoxaemic and hyperoxaemic episodes, and of bradycardia. (defined as a heartrate < 100 for more than 10 seconds)

d) Frequency of FiO2 adjustments during automated control, both made by the controller, and by bedside staff to over-ride the automated system.

e) Overall oxygen exposure (average measured FiO2) .

- To compare the effect of two SpO2 target ranges (91%-95% and 92%-96%) during automated oxygen control on alarm pressure for the caregiver:

Frequency of SpO2 alarms on smartphone

Total duration of SpO2 alarms on smartphone

Study description

Background summary

Hypoxia and hyperoxia during oxygen therapy for preterm infants can result in significant morbidity and mortality. To reduce these risks, continuous measurement of oxygen saturation (SpO2) guides the titration of supplemental oxygen to target SpO2 values of 91-95%. We have previously studied the effect of two automated oxygen controllers (the OxyGenie and the CLiO2) on time spent within a set target range in the COCkPIT trial. We showed a distinct difference in the distribution of oxygen saturation between controllers: the OxyGenie controller had a narrower distribution, with a significant reduction in time above target range when compared to the CLiO2 controller. However, this was accompanied by a disproportionally smaller increase in time spent under target range (15% during Oxygenie control, 9% during CLiO2 control). These differences may partly be explained by the tendency for the OxyGenie controller to target the midpoint of the target range (93% in case of a target range of 91%-95%). In contrast the CLiO2 controller, according to its patent, targets a SpO2 value of 94% while in target range. Considering the non-linearity of the oxygen tension and oxygen saturation relation (oxygen dissociation curve), it is possible that aiming for a higher target range while using automated oxygen titration will result in less time spent under the target range and fewer target range deviations.

Study objective

To compare the effect of two target ranges (91%-95% and 92%-96%) while on automated oxygen control on the time spent under the target range in preterm infants.

Study design

Randomised cross-over study.

Intervention

In both groups supplemental oxygen will be titrated by the OxyGenie automated oxygen controller for 25 hours, either titrated to a target range of 91%-95% or 92%-96%. Automated oxygen control aimed at a range of 91%-95% is standard of care in our unit.

Study burden and risks

There is no additional burden for the patient as no extra interventions are required.

A more stable SpO2 and fewer desaturations may reduce the risk of associated morbidity. Considering the very short study period (25 hours on the interventional target range), the behaviour of the oxygen controller while within target range, and the unlikeliness of hyperoxaemia while on the upper limit of the target range there are no additional risks of this study.
Preterm infants often need respiratory support and supplemental oxygen for a prolonged period of time. Oxygen is often titrated in order to maintain 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

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Born between 24-32 weeks of gestation receiving respiratory support and supplemental oxygen (at least 25%), with written informed parental consent.

Exclusion criteria

Major congenital anomalies or arterial hypotension requiring vasopressor therapy within 48 hours prior to enrolment.

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:	Recruiting
Start date (anticipated):	09-10-2021
Enrollment:	27
Type:	Actual

Medical products/devices used

Generic name:	SLE6000 respirator with OxyGenie oxygen controller
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-07-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL77097.058.21