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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26938

Source
Nationaal Trial Register

Brief title
OPeRATIOn

Health condition

Neonatal respiratory insufficiency

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Frequency of hypoxic episodes (SpO2 <80% for 1 second or longer)

Secondary outcome

Time SpO2 spent in allocated target range, or above when set FiO2 <0.22.
Time SpO2 spent under 91%.
Time SpO2 spent in range 91%-96%, or above when set FiO2 <0.22.
Time SpO2 spent above 96% when set FiO2 >0.21.
Coefficient of variation of SpO2.
Time in hypoxaemic SpO2 ranges (SpO2 85%-90%, 80-84%, <80%).
Time in hyperoxaemic SpO2 ranges (SpO2 97%-98%, >98%) when set FiO2 >0.21.
Duration of hypoxaemic episodes (SpO2 <85% and <80%).
Frequency of hypoxaemic episodes (SpO2 <85% and <80%) for ≥30 seconds and ≥60 seconds.
Duration of hyperoxaemic episodes (SpO2 >96% and >98%) when set FiO2 >0.21.
Frequency of hyperoxaemic episodes (SpO2 >96% and >98%) for ≥30 seconds and ≥60 seconds when set FiO2 >0.21.
Frequency of bradycardic episodes (HR <100 bpm for ≥10 seconds).
Average oxygen exposure (average measured FiO2)
Coefficient of variation of FiO2
Frequency of SpO2 alarms on smartphone
Total duration of SpO2 alarms on smartphone

Study description

Background summary

A randomised crossover study comparing the effect of two oxygen saturation target ranges on time spent under the target range while preterm infants are on automated oxygen control. We will investigate whether

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

We postulate that a set target range of 92%-96% will result in a more stable SpO2 and accompanying reduction of time spent with an SpO2 <91% and similar or less time >96% when compared to a target range of 91%-95%.

Study design

Outcome parameters (SpO2, FiO2, HR, frequency and duration of alarms) will continuously be monitored at a frequency of 1Hz by the standard bedside monitoring (Philips MP70) system throughout the two days of study participation.

Intervention

Interventional target range: OxyGenie automated oxygen controller set to target an SpO2 of 92%-96% for 25 hours, including a 1 hour wash-out period after a change in set target range.
Standard target range: OxyGenie automated oxygen controller set to target an SpO2 of 91%-95% for 24 hours, excluding a 1 hour wash-out period after a change in set target range.

Contacts

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Eligibility criteria

Inclusion criteria

• Born between 24 weeks 0 days and 31 weeks and 6 days gestation.
• Receiving respiratory support (mechanical ventilation, HFO, NCPAP, NIPPV, or HFNC).
• Receiving supplemental oxygen (defined as FiO2 ≥ 0.25) at the time of enrolment and for

at least 18 hours during the previous 24 hours; Or a coefficient of variation in supplemental oxygen of ≥ 0.1 in the previous 24 hours.
• Expected to complete the 49-hour study period in the current form of respiratory support.
• A postnatal age of less than 36 weeks.
• Written informed parental consent.

Exclusion criteria

• Major congenital anomalies
• 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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-10-2021
Enrollment:	27
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-03-2021

Application type: First submission

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
NTR-new	NL9662
Other	METC Leiden Den Haag Delft : P21.038

Study results