Optimal target range of the CLIO2

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25169

Source
NTR

Brief title
OPTICLIO study

Health condition

Preterm infants, hyperoxemia, hypoxia, desaturation, oxygen saturation targets, closed loop inspired oxygen, CLIO.

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary outcome variable is defined as the proportion of time for all three target ranges with SpO2 within the assigned saturation ranges currently used in the clinical setting, being 86%-94%, minus time with SpO2 above the assigned target range while FiO2 is set at 0.21.

Secondary outcome

Several secondary endpoints will be collected and calculated:
1. the proportion of time in between the FiO2 adjustment periods a) hypoxemia defined as SpO2 < 80% and b) hyperoxemia defined as SpO2 > 98% while FiO2 > 0.21 between the different target ranges.
2. the distribution of SpO2 between the three different periods of target ranges of automatic adjustment of FiO2. This will specifically include the comparisons of the 5th, 25th, 50th, 75th, and 95th percentiles.
3. the fraction of inspired oxygen between the three periods of targets ranges of automatic adjustment of FiO2. For this, the mean, standard deviation, median interquartile and hourly-median FiO2 will be calculated over each recording period.
4. the proportion of time with FiO2 at 0.21 between the three periods of target ranges of automatic adjustment of FiO2.
5. the variability of SpO2 between the three periods of target ranges of automatic FiO2 adjustment. This will specifically include the coefficient of variation (Standard deviation divided by the mean) of SpO2 over each recording period.
6. the frequency and duration of episodes with SpO2 below the target range between the three periods of different target ranges of automatic FiO2 adjustment.
7. the proportion of time with SpO2 below the target range between the three periods of of different target ranges of automatic FiO2 adjustment. This will specifically include the proportion of time with SpO2 below the target range, SpO2 < 80%, SpO2 < 70%, SpO2 between 80-86%, and SpO2 between 80 % and the lower limit of the assigned target range.
8. the frequency and duration of episodes with SpO2 above the target range between the three periods of automatic FiO2 adjustment.
9. the proportion of time with SpO2 above the target range while FiO2 > 0.21 between the three periods of different target ranges of automatic FiO2 adjustment.
10. the oxygen saturation status following pulse oximeter signal drop-out between periods of automatic FiO2 adjustment. The oxygen saturation status will be defined as SpO2 within, above or below the assigned target range for at least 10 seconds within the first minute after drop-out ends (i.e. Initial status) and at least 60 seconds over the first two minutes after the drop-out ends (i.e. Persistent status).
11. the rate of overshoot status following episodes when SpO2 decreased below the target range between periods of automatic FiO2 adjustment. This will be defined as SpO2 above the target range for at least 10 seconds over the first minute following recovery from an episode of SpO2 below the target range (Initial overshoot status) and as SpO2 above the target range for at least 60 seconds over the first two minutes following recovery from an episode of SpO2 below the target range (Persistent overshoot status).

Study description

Background summary

Both hypoxia and hyperoxia can lead to organ damage in preterm infants. For this reason the transcutaneously measured oxygen saturation (SpO2) is kept within a range between 86% and

95%. Hypoxia is mainly caused by immature or impaired control of breathing (apnea) and/or a compromised lung function. Hypoxia is often treated with supplemental oxygen, which is manually adjusted to keep the SpO2 within the target range. However, due to clinical instability and the limited time nurses have to adjust the amount of oxygen, preterm infants only spent approximately 50% of the time within the SpO2 target range. Recent studies have shown that the automatic fractional inspired oxygen (FiO2) function of the AVEA ventilator is more capable of maintaining preterm infants within preset saturation ranges than manual adjustment. However, it is unknown to what extent narrowing the SpO2 target range during automated control will result in a tighter control of the SpO2.
This randomized controlled cross-over trial will assess the optimal target range of the automatic FiO2 function by maintaining the same mean, and narrowing the upper and lower limits of the target range.

Study objective

Both hypoxia and hyperoxia can lead to organ damage in preterm infants. For this reason the transcutaneously measured oxygen saturation (SpO2) is kept within a range between 86% and 95%. Hypoxia is mainly caused by immature or impaired control of breathing (apnea) and/or a compromised lung function. Hypoxia is often treated with supplemental oxygen, which is manually adjusted to keep the SpO2 within the target range. However, due to clinical instability and the limited time nurses have to adjust the amount of oxygen, preterm infants only spent approximately 50% of the time within the SpO2 target range. Recent studies have shown that the automatic fractional inspired oxygen (FiO2) function of the AVEA ventilator is more capable of maintaining preterm infants within preset saturation ranges than manual adjustment. However, it is unknown to what extent narrowing the SpO2 target range during automated control will result in a tighter control of the SpO2. The hypothesis of this trial is that narrowing the target range of the automatic FiO2 function by maintaining the same mean, and narrowing the upper and lower limits of the target range, will result in an increased proportion of time within the target ranges.

Study design

Not applicable

Intervention

Infants enrolled in the study will randomly undergo three study periods of 24 hours each by the automatic function in the AVEA ventilator, one with target ranges of SpO2 set to 86% (lower limit (LL)) to 94% (upper limit (UL)), one with target ranges of SpO2 set to 88% LL and 92% UL SpO2, and one with target ranges of SpO2 set to 89% (LL) and 91% (UL). Random assignment to each target range of SpO2 will be done immediately prior to the start of the study procedures in each enrolled infant. In order to minimize the effect of the previous
assigned target range, the infants will receive 24 hours of standard care switching off the automatic function after the first and second target range during 24 hours as a wash-out period. Infants will remain in the study for a period of 120 hours. At the end of which, they

will exit the study.

Contacts

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Eligibility criteria

Inclusion criteria

Preterm infants, born with a gestational age between 23 and 32 weeks, and a weight at study entry between 0.4 to 4 kilograms, needing non-invasive respiratory support by the AVEA ventilator with a supplemental oxygen > 0.21 for more than 18 hours per day.

Exclusion criteria

The eligible preterm infants will not have one of the following 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, or if the

attending physician deems participation in the study is not in the best interest of the infant

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2014
Enrollment:	41
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-01-2014
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	NL4224
NTR-old	NTR4368
Other	2013_217#B2013801a : METC ID

Study results

Summary results
None