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

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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 96% when compared to a target range of 91%-95%.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26938

Bron
NTR

Verkorte titel
OPeRATIOn

Aandoening

Neonatal respiratory insufficiency

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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%.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Leiden University Medical Center
Hylke Salverda

+31715298862

Wetenschappelijk

Leiden University Medical Center
Hylke Salverda

+31715298862

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

• Major congenital anomalies
• Arterial hypotension requiring vasopressor therapy within 48 hours prior to enrolment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-10-2021
Aantal proefpersonen:	27
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9662
Ander register	METC Leiden Den Haag Delft : P21.038

Resultaten