Prolonged automatic oxygen support in preterm infants

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Preterm infants often require supplemental oxygen to prevent hypoxemia and hyperoxemia. Conditions that have been associated with organ damage and an increased mortality. Newly developed techniques incorporated in the ventilator provide the...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27305

Bron
NTR

Verkorte titel
OPTICLIO 2 study

Aandoening

hypoxemia, hyperoxemia, hypoxie, hyperoxie

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Amsterdam
Overige ondersteuning: Academic Medical Center (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The hypotheses of this trial are based on the need to assess the effectiveness of A-FiO2 adjustments over time. The primary outcome variable is therefore defined as the proportion

of time for both control settings with SpO2 within the assigned saturation TR (87-95%), measured over a time period of maximum 28 days and excluding time with SpO2 above the range while FiO2 is set at 0.21.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Preterm infants often require supplemental oxygen to prevent hypoxemia, a condition that has been associated with organ damage and an increased mortality. However, too much oxygen supplementation resulting in hyperoxemia may lead to systemic oxidative damage and long-term complications such as retinopathy of prematurity (ROP). For these reasons, oxygen saturation is continuously measured in preterm infants with pulse oximetry (SpO2) aiming to keep it within a safe target range (TR) by manually titrating the fraction of inspired oxygen (FiO2). However, studies in preterm infants have shown that SpO2 targeting is a clinical challenge with patients spending only 50% of the time within their SpO2 TR, due to clinical instability and the limited time nurses have to adjust the amount of oxygen. Newly developed techniques incorporated in the ventilator provide the opportunity of automated FiO2 control (A-FiO2). Only short term studies (days) have investigated the A-FiO2 function and long term effects need to be evaluated. The short term studies indicate that this closed-loop A-FiO2 reduces time outside the TR, decreases number and duration of hypo- and hyperoxemic episodes, and reduces caregivers' workload compared to manual FiO2 control (M-FiO2).

Objective: To assess the effectiveness of continuous, long term (weeks) use of a closed-loop FiO2 control system in comparison with M-FiO2 control in preterm infants with non-invasive respiratory support.

Study design: Randomised controlled trial.

Study population: Preterm infants treated in a level III NICU.

Intervention: In order to study the effectiveness over a longer period of time of the A-FiO2 function of the ventilator, preterm infants will be set at random to either continuous use of the A-FiO2 function or to continuous use of M-FiO2 control from first week of life till the 28th day of life.

Doel van het onderzoek

Preterm infants often require supplemental oxygen to prevent hypoxemia and hyperoxemia. Conditions that have been associated with organ damage and an increased mortality. Newly developed techniques incorporated in the ventilator provide the opportunity of automated FiO2 control (A-FiO2). The hypotheses of this trial are based on the need to assess the effectiveness of A-FiO2 adjustments over time. The primary outcome variable is therefore

defined as the proportion of time for both control settings with SpO2 within the assigned saturation range (87-95%), measured over a time period of maximum 28 days and excluding time with SpO2 above the range while FiO2 is set at 0.21.

Onderzoeksopzet

Not applicable

Onderzoeksproduct en/of interventie

Infants enrolled in the study will randomly be assigned to either the A-FiO2 function when receiving non-invasive respiratory support from the ventilator with closed-loop or to the routine M-FiO2 function by the nurses when receiving non-invasive respiratory support. Duration of the intervention per patient will be from randomization to 28 days of age.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Preterm infants will be enrolled based on the following inclusion criteria:

• From day 7 of life after being born with a gestational age under 28 weeks

• Impaired control of breathing (apnea) of at least 2 times / 8 hours, requiring an increase in FiO2 ≥ 20%

• Written informed parental consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Major congenital anomalies

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

• No ventilator with A-FiO2 function available

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2017
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-10-2017
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	NL6543
NTR-old	NTR6731
Ander register	: METC 2017_222

Resultaten

Samenvatting resultaten
None