Comparing CPAP Titration Strategies in very preterm infants at birth

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To compare the effect of a HCPAP with LCPAP on oxygenation in the first 5 minutes during stabilization in preterm infants at birth.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON49590

Source
ToetsingOnline

Brief title
Comparing CPAP Titration Strategies

Condition

- Neonatal and perinatal conditions

Synonym
Prematurity, preterm birth

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: VIDI beurs

Intervention

Keyword: CPAP, neonatal stabilisation, Preterm, respiratory support

Outcome measures

Primary outcome

Primary outcome oxygen saturation in the first 5 minutes after birth.

Secondary outcome

Secondary outcome: (physiological parameters) are breathing rate and inter-breath variability, minute volume, SpO2 at 5 minutes after birth, SpO2/FiO2 ratio, heart rate, expired tidal volumes during spontaneous breathing, duration below oxygen saturation target range, heart rate and duration of bradycardia, occurrence and duration of positive pressure ventilation given, supplemental oxygen and incidence and timing of caffeine administration in the delivery room. Mortality and short term morbidities will be noted (surfactant administration, pneumothorax, intubation rate, intraventricular hemorrhages, spontaneous intestinal perforations, death).

Study description

Background summary

Continuous positive airway pressure (CPAP) is routinely used in the delivery room to support spontaneous breathing of preterm infants. Although international guidelines currently recommend 5-8 cm H2O CPAP in the delivery room, data to support this recommendation is limited and the optimal CPAP strategy is unknown. In preterm rabbit and lamb models we demonstrated that using a dynamic CPAP strategy is more effective for supporting spontaneous breathing. Using an initially high CPAP-level of 15 cm H2O promoted lung liquid clearance and lung aeration. Once lung aeration and breathing has been established CPAP level can be lowered as a CPAP level of 8 cm H2O will be enough to prevent lung liquid return and maintain lung volume. This high-level CPAP strategy (HCPAP) has shown to improve breathing effort and oxygenation. We hypothesize that this dynamic high CPAP strategy of 15-8 cm H2O is more effective in supporting preterm infants at birth than the currently used low-level CPAP 5-8 cm H2O (LCPAP). Before performing a large clinical trial we

will perform a small clinical trial to verify the preclinical findings of HCPAP in preterm infants at birth.

Study objective

To compare the effect of a HCPAP with LCPAP on oxygenation in the first 5 minutes during stabilization in preterm infants at birth.

Study design

Single center randomized controlled study

Intervention

HCPAP vs low LCPAP strategy.

Infants allocated to the HCPAP (intervention group) will start on 15 or 8 cm H2O CPAP depending on their breathing effort directly after birth. Infants with poor breathing effort will initially receive 15 cm H2O CPAP which will be titrated to 8 cm H2O (in steps of 2-2-3 cm H2O per minute) after the infant i) is breathing on CPAP ii) reached a SpO2 * 85% with FiO2 * 0.4 and iii) heart rate * 100 bpm. Infants with good breathing effort will start with 8 cm H2O CPAP directly.

Infants allocated to the LCPAP (control group) will receive initially 5 cm H2O CPAP, but can be titrated to up to 8 cmH2O depending on their breathing and oxygenation. This is conform local guideline.

Study burden and risks

The burden and risk are expected to be equal between the groups based on preclinical experiments. The optimal CPAP strategy to support breathing of preterm infants at birth is currently unknown and the current recommendation of 5-8 cm H2O is largely based on dogma. CPAP of 5-8 cm H2O CPAP may be insufficient to support breathing increasing the need of positive pressure ventilation, supplemental oxygen and intubation, which have the potential to injure the preterm lungs and brain. Initiating respiratory support with high CPAP and down-titration after lung aeration fits more with the changing lung characteristics during the cardiopulmonary transition at birth and is supported by animal data. Animal research showed that high CPAP improves the oxygenation while reducing the supplemental oxygen requirement. If successful, this strategy could reduce the need for invasive respiratory support.

The burdens associated with participation are minimal as all infants born before 30 weeks gestational age already receive CPAP at birth. We also expect the risks to be minimal as none of the animal studies in spontaneous breathing

lambs and sheep shown an increased risk when using 15 cm H2O CPAP. Also, a retrospective study in the LUMC has shown that circa 80% of the preterm infants receive ventilation directly at birth when they are supported with 5-8 cm H2O CPAP. During ventilation the mean airway pressure is already 15 cm H2O CPAP, thus the CPAP of 15 cm H2O will not be higher than the pressure that the majority of the infants already receive as standard of care.

The results of this pilot study will directly be translated to a protocol for a larger clinical trial using clinically important outcomes. As most preterm infants born need stabilization and respiratory support at birth, this trial will affect treatment of many preterm infants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants are eligible when they are born premature (24 0/7 to 29 6/7 weeks of gestation).

Exclusion criteria

Exclusion criteria are significant (congenital) malformations/abnormalities influencing the cardiopulmonary transition at birth. Also, parents who are not sufficient in Dutch or English will not be approached for participation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2019
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO

Date:	14-10-2019
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	20-01-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	10-09-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	15-04-2021
Application type:	Amendment
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	NL69976.058.19
Other	NTR, NL8089