CPAP titration at birth

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21110

Source
NTR

Brief title
CulTuS

Health condition

Preterm birth

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Arjan te Pas is recipient of a NWO innovational research incentives scheme (VIDI 91716428).

Intervention

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

Objective
To compare the effect of a High-CPAP (HCPAP) with Low-CPAP (LCPAP) strategy on oxygenation in the first 5 minutes during stabilization in preterm infants at birth.

Study design
Single center randomized controlled study

Study population
Infants (n=42) born at 24 0/7 to 29 6/7 weeks of gestation

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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness
The burden and risks 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. If successful, this strategy could reduce the need for positive pressure ventilation, supplemental oxygen and intubation. When maintained, CPAP level of 15 cm H2O could over expand the lungs, compromising the pulmonary blood flow and increase the risk on pneumothorax. To minimize the risk, Infants with good breathing effort, who likely have already established lung aeration, will not start with 15 cm H2O but directly receive 8 cm H2O CPAP. Infants with poor breathing effort, will initially receive a CPAP-level of 15 cmH2O, but down-titrated to 8 cm H2O CPAP guided by the clinical condition of the infant. 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.

Study objective

We hypothesize that an initial CPAP level of 15 cmH2O followed by down titration to 8 cmH2O is better CPAP strategy for preterm infants at birth when compared to the currently used initial CPAP level of 5 cmH2O followed by up-titration to 8 cmH2O when needed. HCPAP will likely lead to better breathing effort, less hypoxia, need for supplemental oxygen and PPV, without increasing the risk for adverse event, when compared to the current CPAP strategy.

Study design

The first 10 minutes after birth

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 sufficient breathing 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.

Contacts

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Eligibility criteria

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 influencing the cardiopulmonary transition.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2019

Enrollment:	42
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	16-10-2019
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	NL8089
Other	METC Leiden Den Haag Delft : METC LDD P19.054

Study results

Summary results
N/A