A randomized controlled trial of respiratory function monitoring during stabilization of preterm infants at birth

Published: 20-03-2013
Last updated: 24-04-2024

To test the hypothesis that observing the data and waveforms displayed on an RFM during the provision of positive pressure ventilation to preterm infants at birth will increase the proportion of tidal volumes within a predefined *safe range* of 4 -...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Interventional

Summary

ID

NL-OMON37164

Source
ToetsingOnline

Brief title
MONitoR-trial (MOnitoring Neonatal Resuscitation- trial)

Condition

- Neonatal respiratory disorders

Synonym
respiratory distress syndrome in preterm infants at birth

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,laerdal resuscitation Foundation

Intervention

Keyword: birth, preterm infant, respiratory function monitoring, resuscitation

Outcome measures

Primary outcome

The proportion of tidal volumes delivered during manual PPV to an infant within the target range of safe tidal ventilation. The target range of adequate tidal volume is defined as 4-8 mL/kg.

Secondary outcome

Secondary outcomes: clinical

- Rates of endotracheal intubation in the first 24 hours after birth

- The need for circulatory support over first 24 hours (inotropes and fluid boluses)

- Incidence of air leak (pneumothorax, pulmonary interstitial emphysema,or pneumomediastinum) in the first 72 hours, reported by a radiologist masked to the intervention.

- Incidence of abnormal cranial ultrasound findings (i) all intraventricular haemorrhage, (ii) severe - ie. Papile grade III and IV intraventricular haemorrhage, (iii) periventricular leukomalacia

- Duration of endotracheal (ET) ventilation (hours).

- Duration of nasal CPAP (hours).

- Duration of supplemental oxygen therapy (hours)

- Total duration of assisted ventilation (ET, CPAP) in hours

- Incidence of bronchopulmonary dysplasia (BPD) at 36 weeks corrected gestational age defined as the need for supplementary oxygen and/or any form

respiratory support. The severity of BPD will be assessed as proposed by Jobe et al.34 and oxygen reduction test will be performed in case of moderate BPD as described by Walsh et al35.

- Neonatal mortality - death before discharge from hospital.

- Composite outcome of death or BPD

Secondary outcomes: physiological and biochemical measurements

1. Oximetry data on SpO2 and heart rate in the first 10 minutes from birth will be downloaded

2. Duration of significant mask leak (defined as > 60 %) as a proportion of time face mask was used.

3. Significant airway obstruction (defined as a reduction in flow and volume (< 25th percentile of measured VTe with minimal leak during the inflation and typical flattening of the flow waves and the PIP was unchanged) as a proportion of the time face mask is used.

4. Occurrence of inadequate tidal volume (defined as <4 ml/kg) as a proportion of the time face mask is used

5. Oxygen saturation (SpO2) levels between 3 and 10 minutes, recorded by a Masimo pulse oximeter

6. FiO2 changes in the first 10 minutes

7. Total amount of pure oxygen given to the patient (oxygen load) will be calculated taking into consideration birth weight, tidal volume, respiratory rate, FiO2 and timing of stabilisation.

Study description

Background summary

Extremely preterm infants often fail to establish efficient gas exchange independently in the delivery room (DR) and many receive mask ventilation or tracheal intubation and mechanical ventilation. A tight seal between mask and face creating a leak free ventilation circuitis important to provide effective ventilation to the transitioning preterm infant . Leak at the mask may contribute to inadequate ventilation or even failure of the resuscitation. Achieving effective manual ventilation can be difficult because most clinicians are not aware when mask leak or airway obstruction occur.With variable leaks, variable tidal volumes are delivered that may be either inadequate or excessive causing lung injury. Moreover, inadequate ventilation may lead to persistently lower oxygen saturations (SpO2) prompting clinicians to increase FiO2. The newly born infant*s lung is susceptible to pro-oxidant mediated inflammation and administration of supplemental oxygen during neonatal resuscitation has recently been revised to reflect this.

Traditionally, adequacy of ventilation during positive pressure ventilation (PPV) in the DR is assessed by adequate chest rise and an increase in heart rate. This contrasts with the assessment of optimal ventilation in the neonatal intensive care unit. Best practice guidelines from experts state that mechanical ventilation should be guided by a continuous display of airway pressure, gas flow, tidal volume (VT) and gas leak at the endotracheal tube (ETT).

Recently, it has been demonstrated that the use of a respiratory function monitor (RFM) can guide PPV in the DR. Manikin and observational studies have shown that a RFM enabled the clinical team to quickly recognize mask leak, inadequate expired Vt, or airway obstruction.
However, thus far data from large randomized studies on the use of an RFM during neonatal resuscitation are lacking. The use of an RFM in the DR has the potential to improve neonatal respiratory support and reduce lung injury. To prove this, a large randomized trial is needed.

Study objective

To test the hypothesis that observing the data and waveforms displayed on an RFM during the provision of positive pressure ventilation to preterm infants at birth will increase the proportion of tidal volumes within a predefined *safe range* of 4 - 8 mls/kg.

Study design

Multi center, non-blinded, randomized controlled trial

Intervention

Eligible infants will be randomised to either have the respiratory function monitor visible or covered during positive pressure ventilation for resuscitation at birth

Study burden and risks

no extra burden or risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants born will be included in this study if they are between 24 and 27 completed weeks gestation receiving PPV for resuscitation at birth

Exclusion criteria

if they are found to have a congenital abnormality
or condition that might have an adverse effect on breathing or ventilation, including: congenital
diaphragmatic hernia, tracheo-oesophageal fistula or cyanotic heart disease.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2013
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	respiratory function monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-03-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	28-11-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-01-2018
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	NL43055.058.12