Non-invasive respiratory function measurements of changes in functional residual capacity and adequacy of tidal volumes in preterm infants at birth

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1) To investigate whether our current respiratory support improves/recruits FRC in preterm infants at birth by measuring changes in FRC in a non-invasive manner.2) To investigate the adequacy of tidal ventilation during respiratory support in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37649

Source
ToetsingOnline

Brief title
Non-invasive respiratory function measurements in preterm infants at birth

Condition

- Other condition

Synonym
respiratoiry changes at birth and adequacy of respiration

Health condition

respiratoire metingen bij geboorte

Research involving

Human

Sponsors and support

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

Intervention

Keyword: FRC, Neonate, Respiration, Tidal volume

Outcome measures

Primary outcome

1) measurements of changes in FRC.

2) measurement of volumetric CO2 during respiration.

Secondary outcome

none

Study description

Background summary

The transition to air-breathing at birth is vital for infant survival. To establish gas exchange at birth, the liquid-filled airways must be cleared and air has to remain in the lungs at end of expiration (functional residual capacity (FRC)). Preterm infants often fail to create FRC because they have an impaired ability to clear airway liquid and their lungs are surfactant deficient. In the Netherlands, ~2500 infants are born very preterm (<32 weeks gestation) annually and 60% of them need resuscitation. Although research is evolving, current resuscitation guidelines are based on very little data and our knowledge of neonatal transition is largely based on observations, assumptions and extrapolation rather than sound scientific studies.

There is consensus that the key to successful resuscitation is adequate positive pressure ventilation (PPV). The adequacy of PPV is traditional assessed by adequate chest rise, which is very subjective and inaccurate, and increased heart rate. However, we are unaware of the effect of our ventilation approaches on lung volume changes and FRC. To understand the effect and adequacy of our interventions, more knowledge in this field is essential as the

immature lung is highly vulnerable to injury, ventilation immediately after birth may affect long-term morbidity and survival. Animal studies have demonstrated that lung injury can occur during resuscitation with just a few large manual inflations.

Although we have learned from observational studies that preterm infants at birth use specific mechanism for recruit and defend their FRC, the exact mechanisms remain speculative. With the measurements we currently use in the delivery room we are not informed what effect ventilation has on improving FRC. In addition, for adequate ventilation (gas exchange) we currently aim for tidal volumes of 4-6 mL/kg, but this range is extrapolated from data collected later in the Neonatal Intensive Care Unit (NICU).

Recent animal studies have demonstrated that, during lung aeration, the concentration of CO2 in exhaled air increases as the proportion of aerated distal gas exchange regions of the lung gradually increases. The explanation for this finding is simply explained by the fact that when the gas exchange regions of the lung are liquid-filled, no CO2 is exchanged and so no CO2 will appear in the expired air. Gradually, as more and more of the gas exchange regions aerate, the concentration of CO2 in the expired air increases. At this early stage of initiating ventilation, the proportion of aerated gas exchange units is the greatest determinant of CO2 concentration in exhaled air.

To improve our respiratory support in preterm infants at birth, we need to be better informed on the effect of respiratory support on FRC and the adequacy of delivered tidal ventilation.

Study objective

1) To investigate whether our current respiratory support improves/recruits FRC in preterm infants at birth by measuring changes in FRC in a non-invasive manner.
2) To investigate the adequacy of tidal ventilation during respiratory support in preterm infants at birth by measuring non-invasive capnography.

Study design

Prospective observational study performed in the Leiden University Medical Center (LUMC).

Study burden and risks

Recording end-tidal CO2 and RIP bands are not cumbersome, and are not contrary to the interests of the infant and the recording are and will not interfere with the standard treatment procedure that is followed. When the state of the infant is in such a way that the attending neonatologist or resident, who is

treating the patient, finds it necessary the recoridng will not be commenced or will be stopped.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants < 32 weeks of gestation needing respiratory support at birth.

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	30-05-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL39294.058.11