Monitoring fetal-to-neonatal pulmonary transition after birth with transcutaneous electromyography of the diaphragm

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This study has the following objectives:1) To assess if dEMG measurement is feasible during pulmonary transition in the delivery room* Does the signal quality (expressed in heart rate and respiratory rate) of dEMG during the transition agree with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Observational non invasive

Summary

ID

NL-OMON48881

Source
ToetsingOnline

Brief title
BRAHMS - Transition

Condition

- Neonatal respiratory disorders

Synonym
Pulmonary transition, respiratory distress

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electromyography, Pulmonary transition

Outcome measures

Primary outcome

The feasibility of dEMG - recording in the delivery room (Signal quality of dEMG) during pulmonary transition expressed as the accuracy in heart rate and respiratory rate.

Secondary outcome

Secondary endpoints are:

- Description of changes in electrical activity (peak, amplitude, tonic activity, etc.) of the diaphragm during the transition.

- Comparison in timing of heart rate detection acquired by EMG, compared to CI and PO, in order to find out which method is the fastest in detecting heart rate

- Besides heart rate monitoring and breathing monitoring, other parameters from the standard-of-care respiratory function monitor (RFM) are studied as well in order to investigate the effect of respiratory support on diaphragmatic activity.

Study description

Background summary

Directly after birth the lungs are still (partly) filled with amniotic fluids. Most of the fluids are pushed out of the lungs when the infant moves through the birth canal, but a certain amount remains. During the first gasps of air the process of fluid absorption by the pulmonary tissue and subsequent

transportation to the blood starts and in the end the fluids excreted. However, not all infants are successful in this process to clear the lungs of the fluids and start sufficient ventilation and gas exchange. Around 5% of the term infants and 60% of preterm infants fail to aerate the lungs fast enough and require some form of resuscitation. Increasing the intrapulmonary pressure by means of positive pressure (Positive end-expiratory pressure, PEEP) and providing (sustained) inflations are common clinical interventions which increase the odds of a successful transition of the infant.

Studies that investigated the infant during its pulmonary transition suggest that the diaphragm, the primary respiratory muscle, plays a crucial role in the transition. However, till now, no study has investigated the activity of the diaphragm during this first period of life, during e.g. gasping and/or resuscitation of the infant.

When the role of the diaphragm can be objectively assessed, this could improve current methods of guiding the transition, which are mostly based on clinical assessment. In clinical practice skin colour, heart rate estimates and chest excursions remain the primary parameters to guide treatment, even though they can be rather difficult to assess and unreliable.

That is why in this study the electrical activity of the diaphragm will be studied as a new clinical parameter for the monitoring of the transition. The activity can be measured with surface electromyography of the diaphragm (dEMG). Three simple electrodes, similar to the standard chest impedance electrodes, are used for the registration.

Besides measuring the diaphragmatic activity, cardiac activity is picked up by EMG as well. In this case the dEMG signal could serve an additional heart rate monitor (HR-EMG).
This combined approach may have the benefit of both registering quality/quantity of breathing and heart rate. The latter is normally registered by pulse oximetry (HR-PO), but heart rate detection with pulse oximetry can be rather slow (up to 90 seconds for a read-out) and the accuracy in the detection of heart rate is debateable. Furthermore, comparison between HR-EMG monitoring and standard chest impedance monitoring (CI) can be used to describe the accuracy of dEMG as a heart rate monitor. An earlier study in the neonatal intensive care has already proven that EMG can be used for heart rate monitoring, but these measurements were done in much less demanding and stressful circumstances.

Study objective

This study has the following objectives:

1) To assess if dEMG measurement is feasible during pulmonary transition in the delivery room

* Does the signal quality (expressed in heart rate and respiratory rate) of dEMG during the transition agree with the standard monitoring devices for these parameters?
* Hypothesis: the signal quality of dEMG will be sufficient for clinical use during pulmonary transition in the delivery room. dEMG is believed to be feasible and as accurate a heart rate monitor as CI and more accurate than PO.

2) To assess the contribution of the diaphragm to the pulmonary transition after birth
Hypothesis: Diaphragmatic activity is higher during both inspiration and expiration during pulmonary transition, and will show a decrease after a period of time, when breathing becomes more stable and the transition is made.

3) To assess delay of heart rate monitoring with the dEMG technique in comparison with CI and PO
Hypothesis: dEMG based heart rate monitoring will be feasible (objective 1) and will be faster in providing a heart rate than PO and will at least be as fast as standard CI.

4) To assess the effect of changes in respiratory support during the neonatal transition on the dEMG activity
Hypothesis: providing and/or intensifying respiratory support will reduce dEMG activity.

Study design

This will be a prospective observational multi-center cohort study at the delivery room and baby room next to the operating room of the Emma Children's Hospital in Amsterdam and the Willem-Alexander Children*s Hospital in Leiden.
*

Study burden and risks

The study population will not benefit from participating in this research. Participation in the study includes the period after birth only and the measurement is done with a non-invasive technique. This study will expand the understanding of the pulmonary transition in newborn infants and potentially also provide feedback and educate caregivers on their efficiency of resuscitation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

-Infants who are born,older than 26 weeks, and need monitoring of the pulmonary transition
-Written parental informed consent acquired antenatal or deferred.

Exclusion criteria

- Major congenital anomaly that prevents placement of EMG electrodes
- Patients for whom life support will be witheld or withdrawn at birth will not be included

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):	27-07-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	08-06-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL64266.018.18