Work of breathing and respiratory control in preterm infants

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To determine the influence of different nCPAP levels on WOB and electrical activity of the diaphragm and to investigate if these parameters are correlated in preterm infants.

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

Summary

ID

NL-OMON46865

Source
ToetsingOnline

Brief title
Work of breathing

Condition

- Neonatal respiratory disorders

Synonym
diaphragm activity, Work of breathing

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Steun Emma

Intervention

Keyword: Diaphragm, Electromyography, Preterm infants, Work of breathing

Outcome measures

Primary outcome

Changes in work of breathing and electrical activity of the diaphragm at

different nCPAP levels.

Secondary outcome

The correlation of electrical activity of the diaphragm and work of breathing.

Study description

Background summary

Non-invasive respiratory support, in particular nasal continuous positive airway pressure (nCPAP), is widely used in preterm infants to reduce work of breathing (WOB), and thereby minimising the risk of respiratory muscle fatigue and respiratory failure. However, the level of nCPAP support varies considerable * between 0 and 8 cmH2O * during daily care because of pressure loss via an open mouth and during nursing care at which time the infants are taken off nCPAP. The effect of these fluctuations on WOB is unknown. WOB is calculated out of data collected on changes in tidal volume and pleural pressures during normal breathing. Pleural pressures in preterm infants are measured with an oesophageal catheter. There is a need for more easy applicable methods that provide continuous online information on WOB. The diaphragm is the main respiratory muscle and end-organ of respiratory control in humans. Measuring electrical activity of this muscle by transcutaneous electromyography (dEMG) is feasible in preterm infants and might provide important information on WOB. However, this possible correlation between WOB and dEMG in preterm infants has so far not been investigated.

Study objective

To determine the influence of different nCPAP levels on WOB and electrical activity of the diaphragm and to investigate if these parameters are correlated in preterm infants.

Study design

Prospective observational study.

Study burden and risks

For this study, the feeding tube placed in the stomach for clinical use needs to be repositioned in the oesophagus. This procedure will, at most, result in minimal discomfort. The changes in nCPAP level only mimic daily changes over time, therefore posing no extra burden to the patient. This study can only be done in preterm infants because of the specific physiology of the immature respiratory network and immature lung development in this specific population. The study population will not benefit from participating in this research. This study will expand our knowledge on respiratory support in preterm infants what will benefit future care for these patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Born at less than 37 weeks GA
- Supported with nCPAP 4 to 6 cm H2O at time of inclusion
- Maximum FiO2 of 30%
- Stable clinical condition
- Written parental informed consent

Exclusion criteria

- Major congenital anomalies
- Clinical instability requiring frequent interventions by the nursing staff that may interfere with the measurement
- The attending physician considers the infant to be too vulnerable to participate in the study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2017
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO

Date:	06-01-2016
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2018
Application type:	Amendment
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	NL54708.018.15