Titrating to the optimal pressure. Is transcutaneous electromyography of the diaphragm a good measurement to determine the optimal respiratory support, during continuous positive airway pressure (CPAP), in pre-term born neonates.

Published: 11-07-2017
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Primary question:Are dEMG measurements a clinical marker to assess the WOB in preterm born neonates?

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

Summary

ID

NL-OMON45956

Source
ToetsingOnline

Brief title
Optimal pressure during CPAP measured through dEMG in pre-term neonates

Condition

- Neonatal respiratory disorders

Synonym
respiratory support, support of breathing

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CPAP, electromyography, Neonate, non-invasive respiratory support

Outcome measures

Primary outcome

Changes in dEMG signal (in uV); measuring the maximal, minimal and delta (

difference between de maximum and minimum value) values of the dEMG during the

levels of CPAP.

Silverman/ Anderson score measured at 5 and 10 minutes per block.

Secondary outcome

- Vital parameters: heart frequency, saturation, apnea, breathing frequency

Study description

Background summary

At the NICU of the Erasmus MC CPAP is extensively used in the respiratory support for preterm born neonates. The level of CPAP is set in accordance with clinical parameters, such as hart frequency, saturation and signs of respiratory disstress. A reliable clinical parameter, which is representative for the work of breathing (WOB) is missing. Transcutaneous electromyography of the diaphragm is a novel technique that could help us in determining the work of breathing and optimal support level. It measures the electrical activity of the diaphragm (in microVolt) and could give an indication of the increase or decline in work of breathing. The higher the electrical activity the greater the WOB. This technique is already been used in adult and children. It is applicable in pre-term neonates. Valid data of its clinical usefulness are

missing.

Study objective

Primary question:
Are dEMG measurements a clinical marker to assess the WOB in preterm born neonates?

Study design

Three electrodes will be placed in a specific order on the thorax of the patient. Measurements are done with an EMG monitor (the Polybench medical research terminal model A). At the start of actual intervention the patient is placed I a comfortable position and all medical and nursing interventions are postponed during the protocol. A stepwise increment and decrease of CPAP, at intervals of 10 minutes will be made. The adjustment will be 2 cm h20 for each step, starting at 4 cmH20 with a maximum of 8 cm H20. Measurements will take place at 5 and 10 minutes, during a "stable" period. A number of stop criteria are established: discomfort in accordance with the Comfort Neo score, an increase of oxygen need of more than 15% from baseline,desaturation below the minimal threshold of 85% for more than two periods, bradycardia below 100/ min for more than 2 episodes, persistent clinical deterioration as perceived by the attending neonatologist.

Intervention

a stepwise in- and decrement of level of CPAP, between 4-8 cm H20, in blocks of 10 minutes.

Study burden and risks

At the start of the study three extra electrodes are placed on the chest and abdomen of the patient. These electrodes have a dermatologic safe adhesive, which is easily removed. To prevent respiratory failure due to hypo or hyper inflation the stop criteria and clinical condition are leading. If these limits are overridden, the study will be stopped.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- pre-term neonates admitted to the NICU ward.
- supported with CPAP
- clinically stable, for at least 24 hours
- gestational age above 26 weeks and under 32 weeks

Exclusion criteria

- neonates with congenital anomalies
- respiratory support other than CPAP
- gestational age under 26 weeks and above 32 weeks

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2019
Enrollment:	19
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL57715.000.17