Transcutaneous electromyography of the diaphragm of newborn infants

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1. Feasibility and reproducibility of transcutaneous (tc) dEMG on premature neonates. - Are the signal quality (heart rate and respiratory rate), bradycardias and apneas similar to the current impedance monitoring2. Can we differentiate between...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Neonatal respiratory disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41440

Source
ToetsingOnline

Brief title
Neonatal dEMG

Condition

- Neonatal respiratory disorders

Synonym
Control of breathing, diaphragm activity

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NIOF 2010 (noordelijke innovatie ondersteuningsfaciliteit);gefinancierd door het Europees Fonds voor Regionale Ontwikkeling (EFRO) en door het Ministerie van EL&I.

Intervention

Keyword: Diaphragm, Electromyography, Newborn

Outcome measures

Primary outcome

- Feasibility and reproducibility of tc-dEMG on premature neonates

- Differentiation between central versus obstructive apneas with tc-dEMG.

- The effect on diaphragm activity of an upload dose Caffeine or Dopram .

- The effect on diaphragm activity when changing respiratory support from nCPAP

to 'flowsnor'.

- Predictive values of success or failure by change from nCPAP to 'flowsnor'.

- Which role plays the diaphragm during neonatal pulmonary transition.

- Detection of spontaneous breaths by transcutaneous dEMG.

Secondary outcome

Not applicable

Study description

Background summary

The diaphragm is an important respiratory muscle and plays an important role in the neonatal respiration and neonatal pulmonary transition. Transcutane measurements of the electrical activity of the diaphragm (dEMG) gave us insight in the control of breathing in children and neonates. However, the role of the diaphragm in the control of breathing in preterm neonates and during the pulmonal transition in term neonates is unclear. Therefore, dEMG in (preterm) neonates is useful and clinically relevant.

Transcutaneous dEMG in premature neonates is feasible. This research project investigates the physiology of control of breathing, pathophysiology of respiratory disorders, detection of spontaneous breaths and the outcome of respiratory and pharmacotherapy treatments in premature newborns.

The aim of this research project is to achieve improved respiratory monitoring which will lead to improved pulmonary and neurological outcome.
In preterm and in term neonates we also investigate which role the diaphragm plays during the neonatal pulmonary transition. This information is important to determine the need and type of respiratory assistance at birth.

Study objective

1. Feasibility and reproducibility of transcutaneous (tc) dEMG on premature neonates.
- Are the signal quality (heart rate and respiratory rate), bradycardias and apneas similar to the current impedance monitoring
2. Can we differentiate between central versus obstructive apneas with tc-dEMG.
3. What is the effect on diaphragm activity after an upload dose Caffein or Dopram.
4. What is the effect on diaphragm activity when we change respiratory support from nCPAP to the 'flowsnor' and what are the predictive values of success or failure by change from nCPAP to 'flowsnor'.
5. Which role plays the diaphragm during neonatal pulmonary transition measured by tc-dEMG in term neonates.
6. Which role plays the diaphragm during neonatal pulmonary transition measured by tc-dEMG in preterm neonates.
7. Is transcutaneous dEMG superior to the Graseby capsule in detection of spontaneous breaths?

Study design

Observational Prospective Cohort study

Study burden and risks

Burden, benefit and risks:
Although there will be no direct benefits for enrolled patients, the results of this study will improve our knowledge about the diaphragm during respiration and will lead to more optimal treatments for future preterm neonates. Tc-dEMG has been conducted by former investigators on infants and neonates in the Emma Childrens Hospital, AMC and no burden was described. Because of the observational, non-invasive character of tc-dEMG and because no burden was described on infants and neonates, we assume this will be the same for our population.

Group relatedness:
We study the role of the diaphragm in the control of breathing in (premature) newborns. Therefore we can not perform this study in another population than (premature) newborns.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Premature neonates GA < 37 weeks and healthy term infants
Non-invasive respiratory support or no respiratory support
Informed consent of one or both parents

Exclusion criteria

Congenital malformation of thorax, heart and/or lungs
Non-invasive or invasive (endotracheal) ventilation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	23-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-03-2015
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	NL39990.018.12