Minimally invasive surfactant therapy and diaphragm activity in preterm infants

Published: 24-05-2016
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To determine the effect of MIST on the electrical activity of the diaphragm.

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

Summary

ID

NL-OMON46170

Source
ToetsingOnline

Brief title
Minimally invasive surfactant therapy

Condition

- Neonatal respiratory disorders

Synonym
Respiratory distress syndrome, respiratory problems of newborn preterm infants

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Electromyography, Infants, newborn, premature, Respiratory distress syndrome, Surfactant

Outcome measures

Primary outcome

Changes in electrical activity of the diaphragm after MIST

Secondary outcome

Changes in Vt after MIST

The correlation of changes in diaphragm activity and changes in Vt after MIST.

Study description

Background summary

Respiratory distress syndrome (RDS) is a common diagnosis in preterm infants, caused by surfactant deficiency. The treatment consist of respiratory support and exogenous surfactant administration. Traditionally, surfactant is administrated via an endotracheal tube. However, to prevent adverse effects of intubation and mechanical ventilation in spontaneous breathing preterm infants with RDS, minimally invasive surfactant therapy (MIST) becomes more common in clinical practice. During MIST infants are non-invasively supported with nasal continuous positive airway pressure (nCPAP). Clinically, the work of breathing, i.e. tachypnea and dyspnea, decreases after surfactant administration due to the improvement of lung compliance and functional residual capacity (FRC). However, to date this decrease in work of breathing has not been objectified with physiological measurements. Electrical activity of the diaphragm, the main respiratory muscle, can be measured with transcutaneous electromyography (dEMG). This non-invasive, easy to use, bedside monitoring tool is considered to be a measure of work of breathing.

Study objective

To determine the effect of MIST on the electrical activity of the diaphragm.

Study design

Prospective observational cohort study

dEMG and respiratory inductance plethysmography (RIP) are used to measure diaphragm activity and tidal volume (Vt) before, during and after MIST procedure.

Study burden and risks

This study can only be done with preterm subjects because surfactant therapy for RDS is only used in this specific population. The study population will not benefit from participation in this research. This study will provide physiological information on the effect of a widely used treatment in preterm infants, which is thought to improve and optimize future care for this patient population. The measurement techniques used are non-invasive and well tolerated.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Born at gestational age < 37 weeks
- Non-invasive respiratory support
- Clinical signs of RDS in first 72 hours after birth
- Indication for MIST based on our hospital protocol and ascertained by the attending physician
- Written parental consent

Exclusion criteria

- Major congenital anomalies
- 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):	22-06-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	24-05-2016
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	NL56594.018.16