Nasal Intermittent Positive Pressure Ventilation in Preterm Infants

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To describe the synchronicity of nIPPV respiratory support with spontaneous diaphragm activity and the effect of asynchrony of mechanical inflations and spontaneous breaths on lung volume, mechanical parameters and diaphragm activity in preterm...

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

Summary

ID

NL-OMON43658

Source
ToetsingOnline

Brief title
nIPPV

Condition

- Neonatal respiratory disorders

Synonym
Asynchrony of spontaneous breathing and respiratory support, diaphragm activity

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: STW

Intervention

Keyword: Asynchrony, Electromyography, Infant, nIPPV, Premature

Outcome measures

Primary outcome

Percentage of synchronicity of ventilator flow cycles and spontaneous breaths of the infant detected by transcutaneous electromyography of the diaphragm (dEMG).

Asynchrony index: defined as asynchronous (not- or insufficiently synchronous) breaths divided by all breaths.

Secondary outcome

dEMG amplitude variations and volume changes measured with respiratory inductance plethysmography between synchronous and asynchronous breaths.

Study description

Background summary

To prevent apnea of prematurity (AOP), respiratory muscle fatigue and respiratory failure, most preterm infants need respiratory support.
Non-invasive respiratory support is preferred in neonatology because invasive ventilation is associated with chronic pulmonary disease and developmental problems. Nasal intermittent positive pressure ventilation (nIPPV) is a non-invasive mode providing positive inspiratory pressure (PIP) as well as positive end-expiratory pressure (PEEP) mimicking endotracheal ventilation. The way nIPPV prevents respiratory failure is unclear and the benefits of synchronizing the mechanical inflation to the patients* spontaneous breaths have not been determined.
Patient-ventilator asynchrony is widely described in adult patients by detecting spontaneous breathing with diaphragm electromyography. Recent studies show adverse effects on respiratory muscle function and clinical outcome. However, in preterm neonates the incidence of patient-ventilator asynchrony during nIPPV is not well described and effects of asynchrony on lung function

and diaphragm have not been studied.

Study objective

To describe the synchronicity of nIPPV respiratory support with spontaneous diaphragm activity and the effect of asynchrony of mechanical inflations and spontaneous breaths on lung volume, mechanical parameters and diaphragm activity in preterm infants.

Study design

Prospective observational study.

Study burden and risks

This study can only be done with preterm subjects because of the specific physiology of the immature respiratory network and immature lung development in this specific population. The study population will not have benefit from participating in this research. This study will provide information on respiratory support in preterm infants, which is thought to improve and optimize future care for these patients. 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 less than 32 weeks of gestational age
- Receiving nIPPV to treat apnea of prematurity
- 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):	17-10-2015
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	01-10-2015
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	NL54199.018.15