

Non-invasive lung function measurements in infants using Forced Oscillation Technique and diaphragm electromyography.

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

Summary

ID

NL-OMON49917

Source

ToetsingOnline

Brief title

Neonatal lung function monitoring

Condition

- Neonatal respiratory disorders

Synonym

respiratory distress syndrome, Respiratory insufficiency

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, Vyaire Medical

Intervention

Keyword: diaphragm EMG, Forced Oscillation Technique, Mechanical ventilation, neonatal lung function

Outcome measures

Primary outcome

Reactance values measured with FOT and diaphragm activity measured with dEMG.

Both techniques are aimed at examination of lung function over time.

Secondary outcome

See primary study parameters

Study description

Background summary

At the Neonatal Intensive Care Unit (NICU) newborn infants may need mechanical ventilation (MV). During MV it is very important that the ventilator pressure levels that are used are be titrated according to the infant's lung function, to prevent atelectasis and improve oxygenation. However, lung function changes due to developing (patho)physiology. In clinical practice, titrating the level of respiratory support is difficult, as there is no standard used technique to monitor the infant's lung function. Therefore, peripheral oxygen saturation (SpO₂) and oxygen demand (FiO₂) are used as secondary measures for adequate gas exchange. However, SpO₂ and FiO₂ are not solely dependent on current lung function and therefore less accurate than desired. With the Forced Oscillation Technique (FOT) an existing lung function measurement has recently become available for neonatal use. Recent studies in infants show that FOT is a feasible method to acquire information on lung mechanics (i.e. airway/lung resistance/reactance), which might prove useful in optimizing respiratory support. Nowadays, FOT is implemented in a neonatal ventilator, which makes it easily accessible. When FOT is performed daily, lung function can be observed over time, is the general hypothesis. In addition, measuring the level of diaphragm activity (measured with transcutaneous electromyography (dEMG)) could prove highly valuable to clinical practice as well. However, never before has this unique and non-invasive combination of methods been investigated in

(mechanically ventilated) infants.

Study objective

This study's first objective is to assess lung mechanics (measured with FOT) in mechanically ventilated infants, in the clinical practice of the NICU, with intermittent measurements during the entire period of mechanical ventilation. The FOT results will be compared with changes in SpO₂ and FiO₂. The second objective is to measure diaphragm activity after the first day of MV and prior to the ceasing of mechanical ventilation (extubation), to assess how diaphragm activity changes with the recovery of the patient. Lastly, exploratory analysis will be performed to determine to what extent a combination of information acquired with EMG and FOT could be of additional value in care for ventilated infants.

Study design

Prospective, observational cohort study

Study burden and risks

This is a non-invasive observational, prospective study that only uses certified techniques. No changes are made to the caregiving routine. The study population will not benefit from participating in this study. This study will expand our knowledge on non-invasive ways to measure lung function, which could improve the respiratory support in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Newborns

Premature newborns (<37 weeks pregnancy)

Inclusion criteria

- * Standard monitoring used with ECG electrodes (25/26 weeks postmenstrual age and older)
- * Intubated due to respiratory failure and ventilated for >24h with Fabian HFOi neonatal ventilator with an operational FOT modality
- * Written parental/guardian informed consent

Exclusion criteria

Congenital anomalies that prevent the execution of a dEMG measurement
Asphyxiated infants with therapeutical hypothermia
Receiving nitric oxide therapy
Intubated as part of an end of life decision/ceasing of treatment
Intubation as a consequence of non-pulmonary related surgical intervention

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): 05-02-2022
Enrollment: 30
Type: Actual

Ethics review

Approved WMO
Date: 14-12-2021
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	NL78419.018.21