Monitoring lung fluid clearance and aeration during pulmonary transition after birth

Published: 03-01-2017
Last updated: 11-04-2024

The objective of this study is to obtain physiological data on lung aeration during pulmonary transition in newborn infants.

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

Summary

ID

NL-OMON43044

Source
ToetsingOnline

Brief title
Lung fluid clearance and aeration during pulmonary transition after birth

Condition

- Neonatal respiratory disorders

Synonym
lungaeration, Newborns

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Birth transitition, Electrical Impedance Tomography, Lung function monitoring, Newborns

Outcome measures

Primary outcome

Study parameters/endpoints

Main study parameter/endpoint

1. The change in lung aeration in the first 60 minutes after birth assessed by:

a. End-expiratory lung volume (*EELV)

b. Absolute tidal volume

c. Tidal volume distribution

2. The regional distribution of these changes in EELV and tidal volume

distribution assessed by:

a. Left to right lung ratio

b. Dependent to non-dependent lung ratio

c. Geometric Center of Ventilation (CoV)

d. Silent spaces or percentage atelectasis

Secondary outcome

1. Assess possible differences between the timing of lung aeration between term

and preterm infants based on short and long time constants (*)

2. Assess possible differences between the timing of lung aeration between

infants born via the vaginal route and those born via caesarian section

3. Assess the association between changes in lung aeration and the vital

parameters heart rate and oxygen saturation measured with pulse oximetry

(SpO2). In a subgroup of patients, we will also assess the association between

lung aeration and airway pressure and volume (see study procedure).

Study description

Background summary

During intra-uterine life, the lungs of the human fetus is fluid filled. This fluid is necessary for normal lung development. Clearance of carbon dioxide and delivery of oxygen is governed by the placenta connected to the fetus by the umbilical cord. At the time of birth these conditions change dramatically. The umbilical cord is clamped, thereby stopping gas exchange via the placenta. This means that normal lung function is now necessary for normal gas exchange. This process is called pulmonary transition. To make pulmonary transition a success, the fluid that is still present at the time of birth needs be to cleared from the lungs. Furthermore, the lungs need to be aerated and perfused in order to start normal gas exchange. Based om studies in lambs and rabbit pups, it is assumed that the postnatal breaths taken in the first minutes after birth are most important in clearing the lung fluid and aerating the lungs. During each inspiration air enters the lungs and the fluid is pushed distally via the airways. This latter process is supported by so-called expiratory breaking. During expiratory breaking, the infants builds up high airway pressure by grunting or crying. This facilitates distal movement of the fluid. At that level the fluid enters the interstitial space and is taken up by the lymphatic vessels. If the infant is not spontaneously breathing at the time of birth, the physician needs to support lung fluid clearance and aeration by applying positive pressure breaths via a mask and bag. To mimic expiratory breaking, pressure also needs to be applied during the expiratory phase of positive pressure ventilation (positive end-expiratory pressure (PEEP)). It is clear that the process of pulmonary transition takes time and that it is perfectly normal that during this transition infants slowly turn pink as the lung gets aerated. Under physiological conditions this may take up to 10 minutes. Studies animal models and human infants have suggested that pulmonary transition differs between infants born via the vaginal route and via caesarian section. Furthermore, it has been suggested that fluid clearance and aeration of the lungs is compromised in preterm infants due to immaturity of the lungs. As previously mentioned the physiology of normal pulmonary transition is mainly based on animal models. The most important reason for the lack of human data is the absence of a tool to non-invasively measure changes in (regional) lung aeration at the bedside. This has recently changed with the introduction of a new technique called electrical impedance tomography (EIT). EIT uses 32

electrodes circumferentially placed around the chest wall. A small current is injected between a pair of adjacent electrodes and all other electrodes measure the voltage change. The pair of electrodes used for current injection changes in a rotating manner. One full circle is an EIT scan and all measured voltage changes are used to reconstruct the regional changes in lung impedance (=resistivity to an alternating current). Aeration will have, by far, the largest impact on impedance. EIT has a high temporal resolution (real-time continues imaging of dynamic lung function), is radiation free and can be used at the bedside. EIT has been studied in (preterm) neonates, infants and children. These studies have shown that EIT imaging is feasible in this population and that it provides reliable imaging of regional lung aeration. The two most important parameters obtained with EIT are regional changes in end-expiratory lung volume (EELV) and changes in the distribution of tidal volume (tidal ventilation). Previous studies have reported no adverse effects, making EIT use safe in this vulnerable population. Part of these studies have been conducted in the Neonatal Intensive Care Unit (NICU) of the Emma Children*s Hospital AMC (METC 05/069, METC 2012/079). More recently EIT has taken another important step that allows it to be used the delivery room. The electrodes have been integrated in a belt and no longer need to placed one by one and stick to the skin of the patient. This means that these non-adhesive electrodes can be place completely non-invasively and vary rapidly provide real-time data on lung aeration.
This makes EIT the first monitoring tool that, in theory, should be ably to monitor normal physiological pulmonary transition after birth. Knowledge on pulmonary transition will be extremely valuable for several reasons. First, understanding normal physiology is essential to define abnormal or compromised pulmonary transition. Second, it also allows to identify possible interventions to support pulmonary transition. Studies have suggested that supporting a compromised pulmonary transition may impact the pulmonary outcome of preterm infants.
As a first step this study aims to monitor pulmonary transition in both term and preterm infants born either via the vaginal route or caesarian section.

Study objective

The objective of this study is to obtain physiological data on lung aeration during pulmonary transition in newborn infants.

Study design

This is a prospective observational study conducted in the neonatal intensive care unit of the Emma Children*s Hospital, Academic Medical Center, Amsterdam over a period of 24 months

Study burden and risks

The burden for the included patients are as minimal as possible as it is a observational study with interventions. The improved non-adhesive EIT belt with sutured in electrodes has made the risk of side effects minimal. In literature no side effects have been reported.

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

o Gestational age 25 * 42 weeks
o Written informed consent from both parents or legal representatives

Exclusion criteria

o Postmenstrual age < 25 weeks
o Birth weight < 600 g
o Chest skin lesions preventing placement of electrode belt
o Acute and severe fetal distress with anticipated need for resuscitation after birth

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Generic name:	Electrical Impedance Tomography Device
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	03-01-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-04-2018
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	NL60035.018.16