Identifying optimal lung volume at lowest mean airway pressure during recruitment and weaning from paediatric high-frequency oscillatory ventilation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON43692

Source
ToetsingOnline

Brief title
optimal lung volume at lowest MAP during HFOV

Condition

- Respiratory disorders NEC

Synonym
paediatric ARDS

Research involving
Human

Sponsors and support

Primary sponsor: Kinder Intensive Care

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

Intervention

Keyword: Continious distending pressure, HFOV, PV-loop, Weaning

Outcome measures

Primary outcome

End expiratory lung volume (EELV) measured by RIP and EIT.

Secondary outcome

- Tidal volume generated by the oscillator

- Diaphragm activity

Study description

Background summary

High-frequency oscillatory ventilation (HFOV) is an alternative mode of ventilation that is frequently used in neonatal and paediatric critical care when conventional mechanical ventilation fails. Assessment of lung recruitability during HFOV is difficult and at present guided by subjective clinical parameters including the SpO2.
With this study we want to test the hypothesis that during HFOV, after recruitment of the lung, the RIP signal and tidal volume are useful tools to titrate the lowest optimal CDP with adequate lung volume in pediatric patients with ARDS

Study objective

The primary objective is to assess the association between the EELV measured with RIP and EIT, and to graphically depict the changes in the pressure volume curve during stepwise decreasing the CDP in a recruited lung and correlate these with clinical estimates of lung recruitment (SpO2 and Pa O2) in order to predict the closing pressure of the lung, before effective closure occurs.

Study design

Prospective, observational study without invasive measurements.

Study burden and risks

There are a priori no specific benefits for the patients who participate in the study. We consider the risks associated with this non-therapeutic study acceptable and the burden minimal, based upon the following arguments:
•Blood sample drawing is done via the already present indwelling arterial line, so that no additional venous or arterial punctures are necessary.
•All parameters collected in this study are displayed real-time on either the ventilator or the pulmonary function monitor; only the EIT, RIP and diaphragm activity analyses are performed off-line.
•For the EIT measurements 16 electrodes must be placed circumferentially around the chest; Diaphragma activity is measured with three electrodes placed on the chest; For the RIP measurements two elastic bands are placed circumferentially around the patient*s chest and abdomen. The electrodes are fully comparable with the electrodes routinely used for ECG monitoring; hence they pose minimal burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

*Confirmed diagnosis of peadiatric ARDS orginating from any cause
*Presence of indwelling arterial catheter
*Indication for HFOV identified by the attending physician
*Informed consent obtained from parents or legal caretakers
*Age <12 years

Exclusion criteria

*Weight less than kg
*No indication for HFOV indentified by the attending physician
*Open abdomen or thorax after surgery

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):	23-11-2016
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	05-02-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL51184.042.15
Other	UMCG research register 201501145