Identifying optimal lung volume in paediatric high-frequency oscillatory ventilation: a pilot study

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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-OMON38695

Source
ToetsingOnline

Brief title
HFOV and lung volume

Condition

- Respiratory disorders NEC

Synonym
Diffuse alveolar disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Children, HFOV, Lung mechanics, Recruitment

Outcome measures

Primary outcome

The main study parameter is the end-expiratory lung volume measured using EIT.

Secondary outcome

Secondary study parameters include a) tidal volume generated by the oscillator,

and b) transcutaneously measured pCO2.

Study description

Background summary

Lung volume is the main determinant of oxygenation in diffuse alveolar disease (DAD) during HFOV. This suggests that an open lung strategy (i.e. opening up the lung and keeping it open) in diffuse alveolar disease by (repeated) recruitment manoeuvres (RM) should be considered when switching to HFOV. But at the same time, not all lung diseases are recruitable and in general the potential for lung recruitability is highly variable. This signifies that individual titration of the mean airway pressure generated by the oscillator is indicated when using HFOV. Unfortunately, at present physicians have the SpO2, blood gas analysis, *P and chest radiography at their disposal for evaluating the response of a patient to HFOV. Developments are being made with respect to respiratory inductive plethysmography (RIP) as tools for the determination of the optimal mean airway pressure. Recently, we have completed a study in N = 20 children (NL32761.042.10, METc 2010/091) in whom we have explored if RIP would be a useful tool for monitoring lung recruitment during titration of the mean airway pressure, and if there was a correlation between an increase in RIP signal and the SpO2. Sixteen children showed an increase in RIP signal, suggestive for an increase in end-expiratory lung volume (EELV). However, this increase in RIP signal coincided only in 9 patients with an increase in SpO2. This raises the question what the association is between the increase in RIP signal and a) the increase in EELV, b) the delivered tidal volume, and c) the elimination of CO2.

Study objective

The primary objective is to asses the association between the EELV measured with RIP and EELV volume measured with electrical impedance tomography (EIT). Secondary objectives include a) studying the association between the EELV measured with RIP and the delivered tidal volume generated by the oscillator, and b) studying the association between the EELV measured with RIP and the transcutaneously measured pCO2.

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 en RIP analyses are performed off-line. For the EIT measurements 16 electrodes must be placed circumferentially around 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.
• The sensor that is used for the continuous PTCCO2 measurement is the same that is routinely used in the neonatal intensive care unit, hence they are clinically accepted
• The flowsensor used for the continuous measurement of the tidal volume can be used safely and has a small dead space (0.9 mL) that does not affect gas exchange during HFOV.
• There is no interference with clinical management of the patients for this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

• Confirmed diagnosis of diffuse alveolar disease originating from any cause
• Presence of indwelling arterial catheter
• Indication for HFOV identified by the attending physician
• Age < 12 years
• Informed consent obtained from parents or legal caretakers

Exclusion criteria

• Weight less than 3 kg
• No indication for HFOV identified by the attending physician

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):	01-09-2013
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	13-11-2013
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	NL45359.042.13