Evaluation of the Bicore IITM as a clinical tool for the assessment of optimal continuous distending pressure in 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-OMON34615

Source
ToetsingOnline

Brief title
BiCore II in paediatric HFOV

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: Non-funded onderzoek. De Bicore-II en supplies worden zonder restricties ter beschikking gesteld door de firma CareFusion.

Intervention

Keyword: Continuous distending pressure, HFOV, PV-loop, Recruitment

Outcome measures

Primary outcome

* Pressure-volume curve corresponding with each step in incrementing the

continuous distending pressure

* SpO2 corresponding with each step in incrementing the continuous distending

pressure

* PaO2

Secondary outcome

* the time at which recruitment has stabilized at a given CDP

* discrimination between lung overdistension or worsening of disease (decreased

compliance due to atelectasis)

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.

Study objective

This observational study is designed to test the hypothesis that the Bicore-IITM technology may act as a useful bedside tool during lung recruitment, as well as a tool in the differentiation between lung overdistension or a worsening of disease during HFOV.

Study design

This study is designed as a prospective, observational study without invasive measurements of neonates and children admitted to the intensive care unit and ventilated with the oscillator during the period October 2010 * March 2011. The study is performed at the Beatrix Children*s Hospital/University Medical Center Groningen, Groningen, The Netherlands, the VU university medical center, Amsterdam, The Netherlands, and at the Queen Paola Children*s Hospital, Antwerp, Belgium.

Study burden and risks

There is no risk associated with this study as this is an observational study without invasive measurements. Patients are not subjected to care or procedures other than the usual standard-of-care in the intensive care unit. There are also no specific benefits for the enrolled patients.

Contacts

Public
Universitair Medisch Centrum Groningen

P.O. Box 30.001
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

P.O. Box 30.001
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- diagnosis of diffuse alveolar disease originating from any cause
- Weight < 25 kg
- Presence of indwelling arterial catheter
- Informed consent obtained from parents or legal caretakers

Exclusion criteria

- obstructive airway disease
- weight less than 3 and more and 25 kg

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):	01-01-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	20-02-2013
Application type:	Amendment
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	NL32761.042.10