Effect of neuromuscular blockade on global and regional lung aeration in mechanically ventilated children - a pilot study

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The primary objective is to study differences in global lung aeration as defined by the center of ventilation before and during use of neuromuscular blockade. The secondary objective is to study differences in regional lung aeration before and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON37704

Source
ToetsingOnline

Brief title
Neuromuscular blockade and tidal volume

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Acute lung injury

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, Mechanical ventilation, Neuromuscular blockade, Tidal volume

Outcome measures

Primary outcome

Differences in global lung aeration as defined by the center of ventilation

before and during use of neuromuscular blockade

Secondary outcome

Differences in regional lung aeration before and during use of neuromuscular

blockade

Study description

Background summary

Neuromuscular blockade is often used to facilitate mechanical ventilation in children. However, the use of sustained neuromuscular blockade impairs spontaneous breathing. In mechanically ventilated adult patients, there is cephalid shift of the diaphragm in the dependent lung zones leading to alveolar collapse and hypoxaemia. This has not been studied in critically ill children.

Study objective

The primary objective is to study differences in global lung aeration as defined by the center of ventilation before and during use of neuromuscular blockade. The secondary objective is to study differences in regional lung aeration before and during use of neuromuscular blockade.

Study design

Prospective observational study without invasive measurements.

Study burden and risks

The are no risks associated with this study. Blood samples are drawn from the already present indwelling arterial catheter. For the EIT measurements 16 electrodes are placed circumferentially around the chest of the patient. This is comparable with the use of electrodes for routine continuous ECG measurement.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

• Age between 0 and 12 years
• Need for neuromuscular blockade defined by the attending physician
• Presence of acute lung injury
• weight >= 3 kg

Exclusion criteria

• No need for neuromuscular blockade
• No acute lung injury
• admitted to the neonatal intensive care unit
• premature birth with gestational age corrected for post-conceptional age less than 40 weeks
• congenital or acquired neuromuscular disorders
• severe traumatic brain injury (i.e. Glasgow Coma Scale < 8)
• congenital or acquired paralysis of the diaphragm
• uncorrected congenital heart disorder
• severe pulmonary hypertension

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-08-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	03-08-2012
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	NL39989.042.12