Effects of neuromuscular blockade on transpulmonary pressure and diaphragm activity in paediatric moderate-to-severe acute respiratory distress syndrome: a pilot study

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To test the hypothesis that NMBAs in mechanically ventilated children younger than 12 years of age with moderate-to-severe paediatric ARDS (i.e. oxygenation index > 12 and PEEP > 5 cmH2O despite adequate sedation) reduce the transpulmonary...

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

Summary

ID

NL-OMON45389

Source
ToetsingOnline

Brief title
PedNMB.2

Condition

- Respiratory disorders NEC

Synonym
PARDS

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: EMG, Neuromuscular blockade, PARDS, Transpulmonary pressure

Outcome measures

Primary outcome

Transpulmonary pressure

Secondary outcome

Haemodynamic profile, respiratory system mechanics, metrics for oxygenation,

ventilation and deadspace, and diaphragmatic activity and occurrence of

pendelluft

Study description

Background summary

Paediatric acute respiratory distress syndrome (ARDS) is a manifestation of severe, life-threatening lung injury. Care for paediatric patient is mainly supportive and based on what works in adults and personal experiences, including the use of mechanical ventilation. However, differences in lung physiology and immunology between (young) children and adults suggests that adaptation of adult practices into paediatrics may not be justified. Recently, we found that introduction of neuromuscular blocking agents (NMBA) resulted in immediate improvement in oxygenation without affecting tidal volume distribution. The mechanisms underlying this observation are unknown.

Study objective

To test the hypothesis that NMBAs in mechanically ventilated children younger than 12 years of age with moderate-to-severe paediatric ARDS (i.e. oxygenation index > 12 and PEEP > 5 cmH2O despite adequate sedation) reduce the transpulmonary pressure, decrease the occurrence of patient - ventilator dyssynchrony by reducing the respiratory rate and prevent the occurrence of

pendelluft.

Study design

Prospective observational study with invasive measurements

Study burden and risks

The risks associated with this study are minimal based on the following arguments: patients in the intensive care unit are under constant tight observation, so any change in vital parameters is noted immediately. Furthermore, patients with severe lung injury are commonly deeply sedated, blood samples are only taken from an indwelling arterial catheter, which is already in place for clinical purposes, insertion of the oesophageal catheter poses the same risk as insertion of nasogastric feeding tubes that are inserted during routine care; our unit has advanced experience with inserting these catheters, and electrical impedance tomography and electromyography measurements are non-invasive by nature. It is important to study the effects of neuromuscular blocking agents on patient outcome in the paediatric context. There are numerous differences in lung physiology and immunology between (young) children and adults indicating that adaptation of adult practices into paediatrics may not be justified.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Informed consent
Age younger than 12 years
Need for mechanical ventilation with tidal volume 5 - 8 mL/kg ideal bodyweight and a mimum PEEP level of 5 cmH2O
Early moderate - to - severe paediatric acute respiratory distress syndrome originating from any cause:
• Acute onset of disease, and
• Oxygenation index > 12, and
• One or more (bilateral) infiltrates on chest radiograph, and
• No evidence of left ventricular failure or fluid overload, and
• Within the first 48 hours of diagnosis of PARDS
Indication for continuous infusion of NMBAs at discretion of the attending physician

Exclusion criteria

No informed consent
Continuous administration of neuromuscular blockade prior at the time of meeting the criteria for PARDS
Chronic respiratory failure on home ventilation
Intracranial hypertension
Bone marrow transplantation
Immunocompromised patients (congenital or acquired)
Pre-existing pulmonary hypertension
Congenital heart disease with left - to - right shunting
Cyanotic congenital heart disease
Withdrawal of life - sustaining treatment
Prematurity (gestational age less than 44 weeks when assessed for eligibility)
History of congenital neuromuscular disorder

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2017
Enrollment:	19
Type:	Actual

Ethics review

Approved WMO

Date:	02-03-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	11-03-2020
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

ID: 23189
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL59838.042.16
OMON	NL-OMON23189