Role of a simple lung ultrasound score in defining pulmonary edema during early fluid overload in pediatric mechanically ventilated patients

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To assess whether pulmonary edema as detected by a lung ultrasound B-line score correlates with the occurrence of early fluid overload and oxygenation failure in mechanically ventilated critically ill children.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Electrolyte and fluid balance conditions
Study type	Observational non invasive

Summary

ID

NL-OMON46247

Source
ToetsingOnline

Brief title
Lung ultrasound during fluid overload in children

Condition

- Electrolyte and fluid balance conditions
- Respiratory tract infections

Synonym
fluid overload, lung edema

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Kinder Intensive Care (via Ammodo Stichting)

Intervention

Keyword: children, Critical care, Fluid overload, Lung ultrasonography

Outcome measures

Primary outcome

The primary parameters are the lung ultrasound B-line score, fluid overload (as determined by the cumulative fluid balance and body weight change) and oxygenation indices during the first week of mechanical ventilation.

Secondary outcome

Not applicable.

Study description

Background summary

Fluid overload is a common complication in children who are admitted to the pediatric intensive care for mechanical ventilation. In these critically ill children, fluid overload is associated with adverse outcome, such as longer mechanical ventilation or higher mortality. A large part of the adverse effects of fluid overload is likely related to an increase in extra-vascular lung water (EVLW), indicating pulmonary edema, impeding ventilation and oxygenation. Various methods are used currently to assess pulmonary edema, however all of these have their own drawbacks. Lung ultrasonography is an easy-to-use, bedside, non-invasive diagnostic tool for EVLW with pulmonary edema estimation. Lung ultrasound scores have been shown to correlate well with amount of EVLW in animal settings, as well as a variety of adult clinical settings. EVLW can be seen on ultrasonography as it generates artifacts called B-lines.. In critically ill children, little is known regarding the use of lung ultrasound for presence of pulmonary edema as caused by fluid overload.

Study objective

To assess whether pulmonary edema as detected by a lung ultrasound B-line score correlates with the occurrence of early fluid overload and oxygenation failure in mechanically ventilated critically ill children.

Study design

This study concerns a prospective observational cohort study at the pediatric intensive care unit (PICU) of the AMC. Mechanically ventilated children will be subjected to serial lung ultrasound examinations, aiming to assess the relation between lung ultrasound B-line scores with early fluid overload and oxygenation failure. Similar study protocols will be applied at the adult intensive care units.

Study burden and risks

Lung ultrasound is a harmless, non-invasive diagnostic tool, which is already used with great frequency in intensive care units to assess multiple (disease-specific) aspects of the lung. Also, in the pediatric intensive care unit it is used increasingly in standard clinical care. Due to the known relation between fluid overload and adverse outcomes, an easy detection tool of pulmonary edema using lung sonographymay provide great benefit in clinical care of these patients. Lung sonography does not cause any additional risk or discomfort to the children on mechanical ventilation. Even more so, as all children on mechanical ventilation are sedated in the PICU, ensuring minimal to no burden to participants. On average an examination lasts 5-10 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Admitted to the pediatric intensive care unit (PICU) of the Emma Children*s Hospital, Academic Medical Center, Amsterdam, The Netherlands
- Intubated and mechanically ventilated with inclusion within 24 hours of start of mechanical ventilation

Exclusion criteria

None

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):	27-06-2016
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	06-06-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-08-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL57328.018.16