Effect of balloon volume on oesophageal pressure monitoring in critically ill children: a pilot study

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To study the effects of varying amounts of air and patient position on oesophageal pressure measurements in children with and without lung injury.

Ethical review	Not approved
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON44610

Source
ToetsingOnline

Brief title
Balloon volume and Poes

Condition

- Respiratory disorders NEC

Synonym
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: Balloon volume, Mechanical ventilation, Oesophageal pressure

Outcome measures

Primary outcome

Peak-to-through oesophageal pressure at varying amounts of air in balloon

Secondary outcome

Peak-to-through oesophageal pressure at varying amounts of air in balloon and

body position (supine vs 30° upright

Study description

Background summary

Commercially available catheters (both for pediatric and adult use) are capable of measuring esophageal pressure and display its value on commercially available mechanical ventilators, and are even suitable for use in pre-term born infants. However, the actual value of the esophageal pressure is amongst others influenced by body position and the amount of air that is inflated into the small balloon around the catheter. So far, these influences have not been studied in mechanically ventilated children.

Study objective

To study the effects of varying amounts of air and patient position on oesophageal pressure measurements in children with and without lung injury.

Study design

Non-therapeutic intervention study with invasive measurements

Intervention

Insertion esophageal cathether

Study burden and risks

The burden is negligible and the risks are minimal because the insertion of an oesophageal catheter is to be considered an invasive procedure; however, the procedure itself is comparable to inserting a nasogastric feeding tube that is routinely done in all ventilated patients to ensure nasogastric tube feeding and prevent gastric distension; the potential risk includes nasal bleeding, misplacement (either to deep or not) or * very rarely * mucosal bleeding in the oesophagus. To our best of knowledge, these complications have so far occurred very rarely in our PICU. Misplacement into the trachea is very unlikely because the endotracheal tube is already in place. Nonetheless, we will record any complication that has occurred when inserting the oesophageal catheter. Furthermore, correct position of the catheter is confirmed if the cardiac signal is present in the pressure * time curve displayed by the ventilator. If not, then the oesophageal catheter is removed. If this occurs, the oesophageal catheter is re-inserted only once. The use of additional oesophageal catheters to measure pressure in mechanically ventilated children has been approved by local IRBs (NL26857.078.09; NL24044.029.08). Similar as for any procedure clinically required, wewill measure the Comfort Score prior to insertion of the oesophageal catheter; if necessary the dosage of sedation will be adjusted. The nurse taking care of the patient will insert the catheter; he or she is fully capable of inserting such a catheter. Finally, there is negligible risk of sinusitis caused by obstruction of the ostium due to having temporarily two catheters inserted because the occurrence of sinusitis in young mechanically ventilated children is very uncommon and the study period is relatively short. It is important to study the effects of PEEP in the paediatric context.

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 PEEP >< = 5 cmH2O
* Haemodynamically stable, assessed by the attending physician

Exclusion criteria

No informed consent
* Chronic respiratory failure on home ventilation
* Intracranial hypertension
* Bone marrow transplantation
* Immunocompromised patients (congenital or acquired)
* Pre-existing pulmonary hypertension
* Uncorrected congenital heart disease with left * to * right shunting or cyanotic heart disease
* Single ventricle laesions
* Evidence of esophageal pathology or the inability to pass a combined esophageal balloon/nasogastric feeding tube
* Contraindication to the passage of an esophageal pressure probe by either the oral or nasal route
* Withdrawal of life * sustaining treatment

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Oesophageal pressure manometry
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	28-11-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL61872.000.17