Estimation of the inspiratory effort in mechanical ventilated children in the pediatric intensive care unit

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To validate two less complex techniques, electrical activity of the diaphragm and ultrasound of the diaphragm, compared to the gold standard (transdiaphragmatic pressures) for monitoring diaphragm function and inspiratory effort during assisted MV...

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

Summary

ID

NL-OMON44393

Source
ToetsingOnline

Brief title
INSPEFFORT_PICU

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
inspiratory effort / mechanical ventilation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: onderzoeker heeft aanstelling bij Radboudumc en verricht onderzoek mede als onderdeel van deze aanstelling.

Intervention

Keyword: children, diaphragm, mechanical ventilation, work of breathing

Outcome measures

Primary outcome

Measuring the degree of respiratory effort during assisted mechanical

ventilation in children by means of two non-invasive techniques (electrical

activity of the diaphragm and ultrasound of the diaphragm).

Secondary outcome

not applicable

Study description

Background summary

Mechanical ventilation (MV) is a life saving intervention in patients with acute respiratory failure. Unfortunately, full ventilator support rapidly induces diaphragm muscle fiber injury and atrophy, the main muscle for inspiration, and is commonly referred to as ventilator-induced diaphragm dysfunction (VIDD). To limit the risk of VIDD, clinicians use ventilator modes that allow patients to perform at least part of the total work of breathing when deemed clinically appropriate. In clinical practice, it would be important to quantify the amount of inspiratory pressure generated by the patient and the level of unloading provided by the ventilator in order to prevent ventilator under- or over-assistance. The gold standard reference for the measurement of the pressure developed by respiratory muscles (Pmus) is based on esophageal pressure (Pes) measurement, but this technique is rather complex and prone to errors. In this study two less invasive diagnostic techniques, electrical activity of the diaphragm and ultrasound of the diaphragm, for monitoring diaphragm function and inspiratory effort will be compared to the more invasive gold standard.

Study objective

To validate two less complex techniques, electrical activity of the diaphragm and ultrasound of the diaphragm, compared to the gold standard (transdiaphragmatic pressures) for monitoring diaphragm function and

inspiratory effort during assisted MV in children.

Study design

This study is a single centre non-therapeutic observational pilot study performed in mechanical ventilated children admitted to a pediatric intensive care unit (PICU) at a tertiary university hospital.
Two less complex techniques will be used to measure respiratory effort on the ventilator which will be compared to the gold standard. Measurements will take about 15 minutes each day as long as the patient is on the ventilator.

Study burden and risks

Participation in this study is associated with minimal burden and negligible risks. All mechanical ventilated infants are sedated. Ultrasound for evaluating the respiratory muscles is a non-invasive technique not interfering with the normal clinical care of these infants and is nowadays standard daily care on PICU. No change in sedation level is necessary for study puroses.
In addition no unexpected clinically relevant findings are expected to be found during diagostic techniques performed for the study.
Currently selected ventilated patients are instrumented with an EAdi-catheter (Maquet Critical Care, Solna, Sweden) for monitoring the patient*s inspiratory activity and to detect patient-ventilator dyssynchrony. At our PICU this is commonly used and is part of daily care. For this study, to measure esophageal and gastric pressure, 2 additional balloons are integrated in the EAdi catheter (Neurovent® catheter), so no additional catheter has to be inserted. This Neurovent® catheter is already standard of care at our adult ICU at the NExCOB (Nijmegen expertisecentrum voor Ontwenning van de beademing) and has been used for diagnostic purposes in children at our PICU as well. Furthermore it is routinely used in several studies carried out by our research team without additional risks.
With this study more insight in the respiratory physiology of mechanical ventilated children on PICU is generated and less invasive ways to guide ventilation will be studied. Information about the respiratory (dys)function acquired during MV is an important clinical priority both for diagnostic purposes and to follow patients status over time. Titrating ventilator support to maintain normal levels of inspiratory effort may prevent changes in diaphragm configuration associated with MV.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Mechanical ventilated children with age < 18 years
2. Spontaneous breathing effort on mechanical ventilation
3. Expected duration of mechanical ventilation >= 48 hrs
4. Intention tot insert an EAdi-catheter for clinical purpose

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Neuromuscular disease
- Congenital hernia diafragmatica
- inability to obtain informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2017
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	26-09-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-05-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL62139.091.17