Does the combination of ventilator waveforms and diaphragm and intercostal EMG improve the identification of patient-ventilator-asynchrony in mechanically ventilated children compared with waveforms alone?

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The primary objective is to compare the incidence of patient-ventilator-asynchrony during paediatric mechanical ventilation using ventilator waveforms with PVA detected by using the ventilator waveforms in combination with diaphragm and intercostal…

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-OMON47162

Source
ToetsingOnline

Brief title
Using diaphragm EMG in PVA

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Ventilator interaction

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: Diaphragm EMG, Mechanically ventilated children, Patient-ventilator-asynchrony, Ventilator waveforms

Outcome measures

Primary outcome

The primary objective is to compare the incidence of

patient-ventilator-asynchrony during paediatric mechanical ventilation using

ventilator waveforms with PVA detected by using the ventilator waveforms in

combination with diaphragm and intercostal EMG.

Secondary outcome

-Level and time course of incidence PVA.

-Time course of distribution of type of PVA.

-Level and time course of diaphragm EMG.

-Level and time course of intercostals EMG.

-Level and time course of phase angle distribution.

-Effect of imposed work of breathing on incidence PVA.

Study description

Background summary

Patient-ventilator asynchrony (i.e. a mismatch in the interaction between the

patient*s needs and the ventilator) can lead to considerable patient distress, lead to increase used of sedatives and it also impedes the effectiveness of the ventilator in decreasing respiratory work. Surprisingly, relatively little is known about its incidence in mechanically ventilated children. Previously, we observed that in 30 percent of all breaths some form of patient-ventilator asynchrony occurred. Currently, PVA can be detected in three different ways. At present, the most readily available method to detect PVA is analyzing the waveforms (the pressure-time, flow-time and volume-time waveform) displayed by the ventilator to detect PVA. However, for a true assessment of the occurrence of PVA it is mandatory to know if there is any patient effort before the ventilator delivers a breath. This can be most reliable method by detected by observing oesophageal pressure waveforms. Alternatively, electrical activity of the respiratory muscles has also been used to study PVA. EMG activity * especially of the diaphragm * also indicates patient effort. We hypothesized that the occurrence of PVA in mechanically ventilated children is higher than reported during visual inspection of the pressure * time and flow * time tracings when this is combined with non-invasive diaphragmatic and intercostal muscle EMG monitoring.

Study objective

The primary objective is to compare the incidence of patient-ventilator-asynchrony during paediatric mechanical ventilation using ventilator waveforms with PVA detected by using the ventilator waveforms in combination with diaphragm and intercostal EMG.

Study design

This is a prospective observational study without invasive measurements in a 20 bed tertiary paediatric intensive care facility at the Beatrix Children*s hospital/University Medical Centre Groningen. The study will start February 2015 and is completed by March 31, 2018.

Study burden and risks

There are a priori no specific benefits for the patients who participate in this observational study. There are no risks associated with this study, based upon the following argument:

1. Patients are not subjected to care procedures other than the usual standard-of-care in the intensive care.
2. For the intercostal and diaphragm EMG measurements 5 electrodes must be placed on the chest; The electrodes are fully comparable with the electrodes routinely used for ECG monitoring; hence they pose no risks.
3. For the RIP measurements two elastic bands are placed circumferentially around the patient*s chest and abdomen. These bands pose no risks.

4. For imposed work of breathing measurements a catheter will be inserted in the endotracheal tube. This catheter will pose no risks.

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

Mechanically ventilated children who are able to trigger the ventilator aged 0-18 years.

Exclusion criteria

-premature birth with gestational age corrected for post-conceptional age less than 40 weeks

-congenital or acquired neuromuscular disorders
-congenital or acquired central nervous system disorders with depressed respiratory drive
-severe traumatic brain injury (i.e. Glasgow Coma Scale < 8)
-congenital or acquired damage to the phrenic nerve
-congenital or acquired paralysis of the diaphragm
-use of neuromuscular blockade
-chronic lung disease
-severe pulmonary hypertension

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2015
Enrollment:	83
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-12-2016
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-12-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL46097.042.13