respiratory muscle activity during mechanical ventilation and spontaneous breathing trials

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To optimize ventilator support in critically ill patients admitted to the intensive care unit by monitoring electromyography of the respiratory muscles.

Ethical review	Approved WMO
Status	Pending
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON41031

Source
ToetsingOnline

Brief title
respiratory muscles during mechanical ventilation

Condition

- Muscle disorders
- Neuromuscular disorders
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
respiratory failure due to muscle weakness;

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: electromyography, mechanical ventilation, respiratory muscles

Outcome measures

Primary outcome

The difference in activity of the respiratory muscles between the low and high assist level in mechanically ventilated critically ill patients admitted to the intensive care unit.

Secondary outcome

The difference in activity of the respiratory muscles between mechanical ventilation and spontaneous breathing in critically ill patients admitted to the intensive care uni

Study description

Background summary

For mechanical ventilation, assist modes are considered standard of care. In these modes the contribution of the respiratory muscle activity of the patient to the inspiratory support by the ventilator cannot be determined routinely. This is of clinical importance as a high level of inspiratory support can lead to suppression of muscle activity resulting in disuse atrophy. In contrast, a low level of support can lead to muscle exhaustion. Electromyography (EMG) of the respiratory muscles has been shown to provide an indicator of respiratory loading/unloading in mechanically ventilated patients. In this study electromyography of the respiratory muscles will be obtained to assess the load of the muscles during the different levels of support ventilation. The load of the respiratory muscles during support ventilation will be compared with the load of the muscles obtained during spontaneous breathing trials.

Study objective

To optimize ventilator support in critically ill patients admitted to the intensive care unit by monitoring electromyography of the respiratory muscles.

Study design

This study is set up as a crossover study. Respiratory variables, including electromyography of the respiratory muscles will be acquired during a 120-min trial. As ventilator support Neurally Adjusted Ventilatory Assist (NAVA) will be used. Two levels of assist will be applied: a high assist level (tidal volume 10-12 ml/kg) and a low assist level (tidal volume 6-8 ml/kg) will be applied in random order. The effect of high and low assist on the activity of the respiratory muscles will be compared.The load of the respiratory muscles during NAVA will be compared with the load of the muscles obtained during spontaneous breathing trials.

Intervention

Diagnostic interventions:
Surface Electromyography (sEMG) is a non-invasive technique used to measure muscle activity. With sEMG signals of the respiratory muscles (diaphragm, intercostal and scalene) can be obtained simultaneously without discomfort for the patient. Eight ECG electrodes attached to the muscle sites and connected to a wireless EMG recorder (Dipha-16, Inbiolab, Groningen) are used to obtain signals.
Standard respiratory mechanics, including airway pressure, flow and volume measurements, are obtained with the NICO monitor with the use of a measuring device placed in the ventilator tubings (Philips Healthcare, Best, the Netherlands).

Therapeutic interventions:
Two levels of assist will be applied: a high assist level (tidal volume 10-12 ml/kg) and a low assist level (tidal volume 6-8 ml/kg) will be applied in random order.
A spontaneous breathing trial of at least 10 minutes and maximally 20 minutes will be applied ..

Study burden and risks

Burden associated with participation: the application of extra EKG electrodes for the sEMG measurements and the spontaneous breathing test. Risks: the development of shortness of breath during the spontaneous breathing test.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age >18 yr.
respiratory failure due to severe weakness of the respiratory muscles in absence of pulmonary disease (e.g. myasthenia, cervical spine injury)
respiratory failue de to severe weakness of the respiratory muscles with concomitant lung pathology (e.g. end stage ARDS, COPD and lung transplant)
ability to breathe spontaneously for 10 minutes
written informed consent

Exclusion criteria

Reduced respiratory drive and inability to breath spontaneously without ventilator support for > 10 minutes
Hemodynamic instability defined as blood pressure below 100 / 60 mmHg
Air leaks by cannula or chest tubes: defined as leaks above 1 liter per minute
Severe hypoxemia defined as paO2 below 8 kPa
Esophagus or neck surgery

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2014
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-07-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL48434.078.14