Role of diaphragm fatigue in weaning from mechanical ventilation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Muscle disorders
Study type	Observational invasive

Summary

ID

NL-OMON35029

Source
ToetsingOnline

Brief title
Diaphragm fatigue in weaning

Condition

- Muscle disorders
- Neuromuscular disorders

Synonym
fatigue diaphragm, fatigue respiratory muscles

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diaphragm, EMG, Fatigue, Weaning

Outcome measures

Primary outcome

Main study parameters are the diaphragm efficiency (Edi/Pdi) and tension time

index.

Secondary outcome

Not applicable.

Study description

Background summary

Mechanical ventilation offers essential ventilatory support during acute respiratory failure. Unfortunately, mechanical ventilation is associated with risks and complications and therefore, physicians aim to wean patients from the ventilator as soon as the underlying reason for respiratory failure has resolved. However, 20 - 30 % of intubated patients are difficult to wean from mechanical ventilation, resulting in increased morbidity, mortality and health care costs. The respiratory muscles drive ventilation with the diaphragm as the most important inspiratory muscle. The capacity of the diaphragm of critically ill patients is impaired by ICU-acquired muscle weakness. The combination of an increased load imposed on the respiratory muscles and a reduced capacity to generate pressure results in weaning failure. Although little discussion exists as to whether respiratory muscles are weak in critically ill patients, the development of muscle fatigue during a failed weaning trial is subject of debate. Knowing whether or not patients develop respiratory muscle fatigue would be of major help in planning the timing of the weaning process.

Study objective

The primary objective is to determine whether the diaphragm develops contractile fatigue during a weaning trial and if this is associated with weaning failure. Furthermore, the hypothesis whether diaphragm efficiency (Effdi = electrical activity of the diaphragm (Edi)/ transdiaphragmatic pressure (Pdi)) can be used as an objective predictor for weaning outcome will

be tested.

Study design

A prospective cohort pilot study in mechanically ventilated patients.

Study burden and risks

With the exception of the placement of the esophageal catheter no other experimental interventions will be performed. Introduction of the esophageal catheter may result in mild discomfort. No complications have been reported with the introduction / use of this soft small bore catheter. Furthermore, in the case that neurophysiological measurements have not been performed for clinical reasons, this will be done so for the study purpose. Subjects have no clinical benefits by participating in this study.

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 year or older
- mechanical ventilation for at least 3 days
- the primary physician judges the patient to be ready to be weaned from the ventilator
- informed consent

Exclusion criteria

- pre-existent muscle disease (congenital or acquired) or diseases / disorders know to be associated with myopathy including diabetes and auto-immune diseases.
- upper airway / esophageal pathology (i.e. recent surgery, esophageal varices, diaphragmatic hernia)
- recent (< 1 month) nasal bleeding
- phrenic nerve lesions

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	27-04-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-09-2016
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	NL31719.091.10