The effects of positive end-expiratory pressure on the position, length and function of the diaphragm

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The objective of this study is to evaluate the acute effects of PEEP on the position, length, and contractibility of the diaphragm.

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

Summary

ID

NL-OMON46488

Source
ToetsingOnline

Brief title
Effect PEEP on diaphragm

Condition

- Muscle disorders
- Respiratory disorders NEC

Synonym
N/A

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: diaphragm function, diaphragm weakness, positive end-expiratory pressure

Outcome measures

Primary outcome

The first main parameter is the change in the position of the diaphragm during different PEEP levels, as measured with both ultrasound and MRI. The second parameter is the changes in neuro-mechanical efficiency of the diaphragm (ratio between pressure and electrical muscle activity) during different PEEP levels, as measured with a nasogastric catheter. Furthermore, twitch transdiaphragmatic pressures during different PEEP levels, as measured with magnetic stimulation of the phrenic nerves, will be monitored. At last, changes of the diaphragm*s shape and length during different PEEP levels, as measured with MRI will be used.

Secondary outcome

The secondary study parameters is the difference between diaphragm parameters obtained by ultrasound and parameters obtained by MRI.

Study description

Background summary

In almost all mechanically ventilated patients, positive end-expiratory pressure (PEEP) is used. Its function is to prevent alveolar collapse and to maintain oxygenation. However, it has recently been found by investigators of the VUmc that PEEP may contribute to diaphragm weakness, which is an important problem in the intensive care unit (ICU). Their study showed that mechanical ventilation with PEEP resulted in a caudal displacement of the diaphragm, since PEEP increases the end-expiratory volume. Furthermore, their study in rats showed that this displacement resulted in a reduced fiber length and sarcomere

length on the short term. After rats were ventilated with PEEP for 18 hours, it was found that adaptation of the diaphragm occurred; i.e. the number of sarcomeres were decreased. It is hypothesized that this adaptation may also occur in mechanically ventilated patients. This could lead to problems in weaning a patient off the ventilator, as PEEP is abruptly removed during a spontaneous breathing trial (SBT). This leads to a reduction in end-expiratory volume which would mean that the newly-adapted diaphragm fibers are being stretched. These stretched muscle fibers are not working at their optimal length of the force-length relation, thereby contributing to diaphragm weakness. More insights in the role that PEEP could have on the development of diaphragm weakness in mechanically ventilated patients are needed.

Study objective

The objective of this study is to evaluate the acute effects of PEEP on the position, length, and contractibility of the diaphragm.

Study design

Proof of concept study in healthy subjects

Intervention

Participants will breathe with different levels of PEEP through a non-invasive ventilation (NIV) face mask. During the first part of the study, a nasogastric tube will be inserted and EMG surface electrodes are placed, after which measurement with magnetic stimulation and ultrasound are made during different levels of PEEP. During the second part of the study, MRI measurements are performed during different levels of PEEP.

Study burden and risks

We do not expect high risks for participating in this study, as measurements will be performed on healthy subjects.
PEEP ventilation may be experienced as slightly uncomfortable but is generally well tolerated by a healthy individual. The burden to the subject of placement of a nasogastric catheter used in this study is similar to placement of a regular nasogastric feeding tube. From our clinical and researchexperience, we consider these risks minimal, especially when *high risk subjects* are excluded (upper airway / esophageal pathology, nasal bleeding disorders) and insertion is performed by well-trained nurses or physicians. The insertion of the catheter will take place at a safe environment (research room at the ICU), where potential risks can be anticipated immediately. Therefore, we believe that the risk of the nasogastric catheter is minimal. Furthermore, All other study measurements (ultrasound, magnetic stimulation and MRI) are non-invasive and performed according to clinical protocol. As subjects with possible

contraindications for these measurements are excluded from study participation, we believe that risks are minimal. Subjects do not have direct benefits from participating in this study. However, participation will lead to further knowledge of the effects of PEEP on diaphragm weakness, which can lead to better mechanical ventilation strategies.

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

Signed informed consent
Age * 18 years

Exclusion criteria

Symptoms relating to respiratory or cardiovascular disease
History of pneumothorax or family history of primary pneumothorax
Obesity (BMI > 30)
Known pregnancy
Contraindications for the placement of a nasogastric tube (Upper airwau/esophageal/gastric/mouth or face pathology, nasal bleeding within the last 2 weeks or use of anticoagulants)
Contraindictions for MRI (Electrical/metallic implants, claustrophobia, history in metalworking)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-04-2018
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	22-02-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-08-2018
Application type:	Amendment

Review commission: METC Amsterdam UMC

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	NL63905.029.17

Study results

Date completed: 21-01-2019

Results posted: 14-06-2020

First publication
12-06-2020