Electrical Impedance Tomography guided assist levels during Pressure Support Ventilation: A pilot study

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Primary objective- To define the optimal pressure support level for homogeneous lung ventilation during PSV, based on EIT measurements, in patients with and without lung disorders.Secondary objectives- Improved oxygenation compared to baseline-...

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

Summary

ID

NL-OMON38855

Source
ToetsingOnline

Brief title
EIT guided assist during PSV

Condition

- Pleural disorders

Synonym
acute lung injury, ALI

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: Electrical Impedance Tomography, Functional residual capacity, Pressure Support Ventilation, Transpulmonary Pressure

Outcome measures

Primary outcome

Optimal pressure support level for homogeneous lung ventilation, based on EIT.

Secondary outcome

Artierial oxygenation

Dorsal lung ventilation

Dead-space (based on CO2)

Functional residual capacity

Transpulmonary pressures

Study description

Background summary

From the ARDSnetwork trial we know that controlled mechanical ventilation with tidal volumes of 6mL/kg improves survival. However, during Pressure Support Ventilation (PSV) it is unknown which tidal volume is superior. However, we know that inhomogeneous ventilation of the lung lead to increased stress on the lung tissue, which increases the risk to develope ventilator induced ling injury. In recent research we have shown that PSV with lower assist levels results in more homogeneous ventilation as measured by Electrical Impedance Tomography (EIT). In addition, we showed that during higher assist levels the non-dependent lung region is hyperinflated.

Study objective

Primary objective
- To define the optimal pressure support level for homogeneous lung ventilation during PSV, based on EIT measurements, in patients with and without lung disorders.

Secondary objectives
- Improved oxygenation compared to baseline
- Improved dorsal ventilation distribution compared to baseline
- Reduced amount of dead-space compared to baseline
- Improved FRC compared to baseline
- Lower transpulmonary pressure compared to baseline

Study design

The study is designed as an intervention study.
The level of ventilatory assist will be titrated based on the intratidal gas distribution, calculated from EIT measurements. First a baseline EIT measurement will be performed. Thereafter a pressure support trial will be performed from 0 to 15 cmH2O. From this support trial the best level of assist will be defined as the support level leading to homogeneous ventilation of the lung regions. EIT measurements will be performed twice a day in 3 consecutive days. After 72 hours the study will end. The level of Positive End-Expiratory Pressure (PEEP) level will be set according to the standard FiO2/PEEP table, which is the standard of care on our ICU.

In addition, functional residual capacity, lung compliance, dead-space, blood gasses and transpulmonary pressures will be measured twice a day.

Intervention

Pressure Support level will be set based on Electrical Impedance Tomography measurements, in order to ventilate the lungs homogeneously.

Study burden and risks

Pressure Support Ventilation (PSV) is the standard of care in our mechanically-ventilated patients on the Intensive Care Unit. The EIT guided assist levels could lead to larger tidal volumes. However, during the entire study the pressure alarms will be kept below 30 cmH2O, which have been shown to be safe. Therefore patients participating in this study will not be exposed to additional risk.

An esophagal pressure catheter will replace the standard feeding tube in order to perform transpulmonary-pressure measurements. This is a special feeding tube with a small balloon to measure esophageal pressures during the inspiration and expiration. This special gastric tube can be used to feed the patient. This tube will be placed following the local protocol for feeding tube placement

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

>18 years
Pressure Support Ventilation
Written informed consent legal representative

Exclusion criteria

Thorax drainage
Open thoracic wounds
<18 years of age
Thoracic deformities

Esophageal varices

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-08-2013
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	NL44445.078.13