Lung aeration measured by EIT after a lung recruitment manoeuvre directly after intubation in mechanically ventilated critically ill patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38723

Source
ToetsingOnline

Brief title
Lung aeration after LRM

Condition

- Respiratory disorders NEC

Synonym
Ventilator associated lunginjury

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: electrical impedance tomography, intubation, lung recruitment manoevre, mechanische beademing

Outcome measures

Primary outcome

The primary endpoint is regional lung aeration, assessed by EIT.

Secondary outcome

The secondary endpoint is RV*function measured by contractile *, preload * and

afterload*parameters, assessed by TTE.

Study description

Background summary

Mechanical ventilation using a so*called *open lung* approach has the potential to improve oxygenation, and even to reduce ventilator*associated lung injury, in intensive care unit (ICU)*patients. An *open lung approach* requires recruitment maneuvers (RMs). It is uncertain when to apply RMs: early after tracheal intubation in each patient, or on indication in patients in whom oxygenation worsens. It is also uncertain whether RM compromises cardiac function of ICU*patients.

Methods

Main study parameters/endpoints

Study objective

The primary objective of this study is to compare the effect of a standard and

early RM in newly intubated critically ill patients. The secondary objective is to determine the effect of an early RM on cardiac function. We hypothesize an early RM to have a sustained effect on lung aeration while improving cardiac function.

Study design

This study is a single*center randomized controlled trial of critically ill patients who need tracheal intubation for mechanical ventilation.
Study population

Intervention

Consecutive newly intubated critically ill patients are randomized to ventilation using an early RM (i.e., within thirty minutes after intubation) or ventilation not using an early RM (i.e., a RM is performed only when oxygenation is severely compromised). Lung aeration is determined by electric impedance tomography (EIT), cardiac function by trans*thoracic echocardiography (TTE). EIT and TTE are performed directly after tracheal intubation, after 1 and 2 hours, and after 24 hours.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness
A RM is a safe procedure in experienced hands. In this study only trained and experienced ICU*physicians perform the RMs. Patients who are randomized to early RM could potentially benefit from this study. EIT and TTE are non-invasive, standard procedures in our ICU, and performed when patients are still sedated.

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

All patients who need intubation for mechanical ventilation in the intensive care department

Exclusion criteria

o Age < 18 years
o Presence of a pacemaker or automatic cardiac defibrillator
o Presence of any implantable pumps
o Presence of thoracal drains
o Skin abnormalities impairing attachment of electrodes

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	20-08-2013
Application type:	First submission
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	NL43859.018.13