Lung aeration measured by Electrical Impedance tomography in Mechanically ventilated critically ill patients

Published: 20-12-2011
Last updated: 30-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational non invasive

Summary

ID

NL-OMON35576

Source
ToetsingOnline

Brief title
LEIM

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
Atelectasis; collapsed parts of the lung

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 1. Electrical Impedance Tomography, 2. Regional lung aeration, 3. Critically ill patients, 4. Atelectasis

Outcome measures

Primary outcome

The main study endpoint is the regional lung aeration, assessed by EIT.

Secondary outcome

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Study description

Background summary

Mechanical ventilation is a life-saving strategy in patients with respiratory failure. Nevertheless, mechanical ventilation has the potential to aggravate or even initiate lung injury, causing overdistention of the non-dependent lung regions and repetitive collapse and re-expansion of dependent lung regions. In the intensive care arena many different mechanical ventilation strategies are employed in patients with acute lung injury, in an effort to attenuate this so-called ventilator-associated lung injury.
Electrical Impedance tomography (EIT) can assess and image changes in regional lung aeration at the bedside during a ventilation strategy change. This may make individualized management of mechanical ventilation possible in a safe, radiation-free manner.

Study objective

Our longstanding goal is to assess the clinical applicability and technical feasibility of EIT in mechanically ventilated critically ill patients with acute lung injury. Our aim is to establish changes in regional lung aeration with EIT during changes in intubated and mechanical ventilated critically ill patients.

Study design

Observational study.

Study burden and risks

In this observational study there are no risks involved for participating patients. Patient burden is minimal to none, and comprises of painless placement of an electrical impedance belt around the lower thorax.

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

- Intubation and mechanical ventilation
- Acute lung injury (acute onset, bilateral infiltrates on CXR, PaO2/FiO2<300mmHg and no clinical signs of left atrial hypertension)

Exclusion criteria

- Age < 18 years
- Presence of a pacemaker
- Presence of an automatic cardiac defibrillator
- Presence of any implantable pumps

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2012
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2011
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	NL38496.018.11