Assessment of Atelectasis by Electrical Impedance Tomography during General Anesthesia for Surgery

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

Summary

ID

NL-OMON35898

Source
ToetsingOnline

Brief title
Electrical impedance tomography in during general anesthesia for surgery

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. Ventilator Associated Lung Injury, 4. Atelectasis

Outcome measures

Primary outcome

The main study endpoint is the change in regional lung aeration, assessed by

the electrical impedance tomography.

Secondary outcome

-

Study description

Background summary

Mechanical ventilation is mandatory in patients under general anesthesia. 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 (e.g. atelectasis). Various modesof mechanical ventilation are employed during general anesthesia for surgery in an effort to minimize atalectasis and prevent lung injury caused by mechanical ventilation.
Electrical Impedance tomography (EIT) is a real-time, non-invasive, bed-side, radiation-free continuous imaging technique able to detect changes of regional lung aeration that could be used to guide mechanical ventilation settings.

Study objective

Our longstanding goal is to assess the clinical applicability of EIT in intubated and mechanically ventilated patients. We aim to observe changes in regional lung ventilation during alterations of mechanical ventilation strategies in clinical situations. EIT will be applied in existing interventional trials in the operation room (e.g., PROVHILO; MEC 10/251), assessing regional lung ventilation in non-injured lungs during the interventions (see research protocol of PROVHILO). Moreover, the effects of different strategies on regional lung ventilation in other patient populations can be determined during mechanical ventilation strategies as performed according to standard clinical care.

The main research questions include:
1. Technical feasibility of EIT registration during mechanically ventilation in patients under general anesthesia for surgery.
2. Assessment of changes in regional lung aeration during mechanical ventilation in the interventional trial PROVHILO (MEC 10/251), and future trials comparing different ventilation strategies.
3. Assessment of changes in regional lung aeration during changes in mechanical ventilation therapy according to standard clinical care.
4. Assessment of correlation of changes in regional lung aeration with observed gas exchange and radiological assessments.

Study design

This study concerns non-invasive observations in intubated and mechanically ventilated patients with non-injured lungs in the operation room.

This is a observational study; electrical impenance tomography will be used to observe regional lung aeration changes during interventions in existing interventional trials and in ventilation strategy changes according standard clinical care.

Prior to EIT registration 16 electrocardiographic electrodes will be placed around the thoracic cage at the 5th or 6th intercostal space and connected with an EIT device. EIT data are generated using an electrical current of 5 mA at 50 kHz (equal to ECG registration).
As data analysis of the EIT registrations are presently performed off-line, after the measurements, the ventilator settings applied by the clinician can and will not be influenced.

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 pre-operatively. The patient will not experience any burden of the measurements.

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 because of general anesthesia for surgery

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:	Recruiting
Start date (anticipated):	26-10-2011
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

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
ISRCTN	ISRCTN70332574
CCMO	NL36684.018.11