Visualization of regional lung ventilation using Electrical Impedance Tomography (EIT)

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Primary Objective: To study the options of the PulmoVista 500 system to visualize regional real-time lung ventilation in healthy volunteersResearch questions:- Can the PulmoVista 500 system provide sufficient information regarding regional lung...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thoracic disorders (excl lung and pleura)
Study type	Observational non invasive

Summary

ID

NL-OMON42254

Source
ToetsingOnline

Brief title
Visualizing lung ventilation with EIT (Elektrical Impedance Tomography)

Condition

- Thoracic disorders (excl lung and pleura)

Synonym
Ventilation in healthy lungs

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electrical Impedance Tomography (EIT), Lung ventilation, Regionalization

Outcome measures

Primary outcome

1) The main endpoint of this study is to gain insight in the possibilities of the PulmoVista system to visualize lung ventilation in healthy subjects aged 18-65.

2) Another main endpoint is the effect of different positions on lung ventilation. To this end, healthy subject will be placed in different positions (specified below) and regional ventilation will be assessed using the PulmoVista system

3) The effect of applying CPAP for a short time period will be tested on healthy subjects.

Secondary outcome

1) The number of adverse and serious adverse events will be documented, although it is not expected to occur in this study.

2) Experience of operators working with this technique.

This will be qualitative data and the data will be used to correctly interpret data and to set-up studies in the future.

Study description

Background summary

Rib fractures are common in patients with thoracic trauma and might lead to the necessity of mechanical ventilation due to respiratory insufficiency. This type

of ventilation can however lead to increased lung damage, making closely monitored ventilator device settings essential. These settings are presently based on global lung parameters, which cannot provide detailed information on regional lung ventilation and it can therefore be expected that treatment is not optimal. Current imaging methods for lung ventilation have numerous disadvantages, which increases the need for a technique that can account for these disadvantages. Electrical impedance tomography is a noninvasive technique that provides real-time cross-sectional ventilation images of the lung at the bedside. Literature and experience regarding the use of EIT is scarce. The aim of this study is to assess the possibility of the PulmoVista system in visualizing real-time regional lung ventilation in healthy subjects, wherein this group the effect of different positions and the application of CPAP will be assessed as well.
Hypothesis: We hypothesize that EIT can provide valuable information regarding regional ventilation in healthy subjects. We expect that different positions influences regional ventilation and that this can be visualized by using the EIT technique. In addition we hypothesize that applying a small amount of CPAP leads to increased regional ventilation as visualized by the PulmoVista 500 system.

Study objective

Primary Objective:
To study the options of the PulmoVista 500 system to visualize regional real-time lung ventilation in healthy volunteers

Research questions:
- Can the PulmoVista 500 system provide sufficient information regarding regional lung ventilation in both a graphical and numerical way?
- How do different positions of a healthy subject influence (regional) lung ventilation?
- What is the effect of applying CPAP for a short time period in healthy subjects on (regional) lung ventilation?

There is no gold standard for visualizing regional lung ventilation. Currently, the best way of visualizing lung ventilation is dynamic Computer Tomography (CT-scan). When PulmoVista proves to be a good way for visualizing lung ventilation this might become the gold standard.

Secondary Objective(s):
To study the operators* experiences and opinions in using the system regarding efficiency, usefulness, ease of use and time needed to prepare for the measurements. Practical issues and difficulties in interpreting the data will also be documented.

Information regarding this topic will provide the investigators with an overview on the utilization of the technology. It will be used by the

investigators of this study to correctly interpret gathered data and it will be used to set up studies that will be conducted in the future, i.e. with respect to overcome or cope with difficulties in using the technique resulting from this study.

Study design

Prospective obervational non-invasive study with a duration of two months

For all subjects, a belt containing electrodes is placed on 4th-6th intercostal area of the healty subjects chest while the healthy subject lies in a 30º angle. It is important that subjects lie still during the measurement time as the signal can be contaminated with noise caused by movement.

Healthy volunteers
2a. With and without CPAP: A CPAP level of 5 cm H2O will be applied during 6 minutes after two minutes of normal breathing.
2b. Influence of different angles. The subject lies during 8 minutes in: ,0º, 30º, 45º, Prone position.

Data collection:
Parameters that will be used in this study are:
- Gender
- Age
- BMI
- End-expiratory lung volume
- Tidal volume
- FiO2
- PaO2/FiO2 ratio (kPa)
- Dynamic compliance (ml/cmH2O)
- Functional EIT image (*fEIT)

Study burden and risks

The risk of specific complications during participation is low. The regional ventilation monitoring provided by PulmoVista 500 is non-invasive and without any side-effects. No ionizing radiation is involved. EIT involves minimal preparation so monitoring is established in just a few minutes. Preparation only requires the positioning of a flexible non-adhesive belt around the healty subjects chest. Long-term measurements could lead to skin irritation, the manufacturer therefore advises not to exceed 24 hours of measuring. It is expected that measurements in this study will take 40 minutes, including preparation and termination. This period of time lies beneath 24 hours, so the risk of occurrence of skin irritations is low.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
AZ 6202
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
AZ 6202
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Group 1 (healthy subjects):
1. Age 18-65 years
2. BMI 18.4 * 24.9 kg/m2
3. Gender: both male and female

Exclusion criteria

Group 1 (healthy subjects):
1. Conditions that interfere with respiration e.g.
- asthma
- COPD

- hyperventilation
- Previous claustrophobic conditions
- Recent (<6 months) thoracal trauma
- Recent (<6 months) lungdisease, thorax disease
- Previous allergic reaction on mask ventilation

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):	26-05-2015
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	PulmoVista 500 System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-04-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL52043.068.15

Study results

Date completed:	01-06-2015
Actual enrolment:	16