Non-invasive measurement of lung compliance and transpulmonary pressure during controlled ventilation

Published: 17-10-2016
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The objective of this study is to determine the agreement between the traditional endo-esophageal balloon method and newly proposed volumetric method of determining lung compliance.

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

Summary

ID

NL-OMON43224

Source
ToetsingOnline

Brief title
Non-invasive lung-compliance during controlled ventilation

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
lung compliance, lung elasticity

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: ARDS, lung compliance, mechanical ventilation, transpulmonary pressure

Outcome measures

Primary outcome

The main study parameter is the agreement between the endo-esophageal and

volumetric methods.

Secondary outcome

Secondary parameters are the influence of PEEP step size,

incremental/decremental PEEP step, body position, and lung injury on the

measured lung compliance.

Study description

Background summary

Measurement of the lung compliance is important in personalizing mechanical ventilation on the ICU. The traditional methods of measuring lung compliance * using air-filled endo-esophageal balloons * is widely applied, but is invasive and is prone to systematical errors. A newly proposed volumetric method is non-invasive and should be more precise, but the method has not been validated.

Study objective

The objective of this study is to determine the agreement between the traditional endo-esophageal balloon method and newly proposed volumetric method of determining lung compliance.

Study design

This is a prospective observational study designed to assess the agreement between two methods.

Study burden and risks

An endo-esophageal balloon catheter is placed. The subject undergoes detailed measurements during a pre-determined protocol, in which PEEP and tidal volume is subject to regular changes. The estimated duration is 1.5 hours. Peak pressure and tidal volume are kept below and .
This study can only be performed in sedated patient receiving controlled mechanical ventilation. The cohort should include both lung-healthy subjects and subjects with lung injury. Only ICU patients fulfil these criteria.
The risks of this study encompass the placement of the endo-esophageal catheter. The catheter is very similar to a normal gastric feeding catheter. Risk of injury during placement is deemed small. Mechanical ventilation with high peak pressures or high tidal volumes is deemed detrimental, if applied for a long time. During his study, the subject will be ventilated with high peak pressures (max. 45 cmH2O) and tidal volumes (max. 12 ml/kg Ideal Body Weight) for short periods of time only.

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

Admitted to the Intensive Care Unit
Controlled mechanical ventilation

Exclusion criteria

Air leakage
Hemodynamic instability

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-10-2016
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	NL57317.078.16