herQLUS * Assessment of Lung Aeration by Lung Ultrasound in Intensive Care Unit Patients; Development of a Quantitative Analysis Method

Published: 25-01-2018
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To develop a computer*based algorithm for quantitative LUS analysis that accurately estimates lung aeration. A chest CT-scan will be used as the reference test.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON46372

Source
ToetsingOnline

Brief title
herQLUS

Condition

- Respiratory disorders NEC

Synonym
'increased lungdensity' and 'decreased amount of air in 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: Aeration, Intensive Care, Lung, Ultrasound

Outcome measures

Primary outcome

Lung aeration of the 12 lung regions evaluated through LUS.

Secondary outcome

* Lung aeration as measured by CT

* Estimation of lung aeration by a conventional visual LUS scoring

* Other LUS findings (e.g., pleural line abnormalities, lung pulse, lung

sliding abolition, pleural effusion)

* Indications for chest CT scanning

* Mechanical ventilator settings during the LUS examination and chest CT-scan

* Ventilator parameters

* Hemodynamical parameters

Study description

Background summary

Monitoring of lung aeration is crucial in Intensive Care patients, especially in invasively ventilated patients. The gold standard for measuring lung aeration is chest Computed Tomography (CT). Unfortunately, a chest CT scan is difficult to obtain in invasively ventilated Intensive Care Unit (ICU) patients and cannot be repeated frequently. Lung Ultrasound (LUS) as a point*of*care imaging tool is increasingly used in the Intensive Care Unit setting. Lung aeration by LUS is presently evaluated through semi*quantitative visual scores. Automated quantification could improve accuracy of lung aeration estimations.

Study objective

To develop a computer*based algorithm for quantitative LUS analysis that

accurately estimates lung aeration. A chest CT-scan will be used as the reference test.

Study design

This is a single*center, prospective observational study.

Study burden and risks

Participants will not directly benefit from participation, but burden is absent. Of note, in this study chest CT-scans are never performed for the purpose of this study * they are clinically indicated and follow the standard protocol for chest CT-scans in critically ill patients. In addition, LUS is a non*invasive procedure without additional risks, and the skin markers used in this study are safe and without burden for patients.

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 for adults of the Academic Medical Center in Amsterdam, The Netherlands
* Receiving invasive ventilation
* Having a chest CT-scan performed on a clinical indication

Exclusion criteria

* Age < 18 years
* Lung Ultrasound (LUS) not feasible (e.g., severe chest trauma, extensive burns on the thorax, open wounds on the thorax)
* No written informed consent of the patient or his/her formal representative
* Reported allergy to skin tape, necessary to attach the skin markers to identify fields at chest CT scans

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):	15-02-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-01-2019
Application type:	Amendment
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

ID: 29300
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64089.018.17
OMON	NL-OMON29300