Advanced lung ultrasound to differentiate pneumonia and atelectasis in ICU patient

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21456

Source
NTR

Brief title
ALUS

Health condition

Pneumonia, Atelectasis

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Sensitivity, Specificity, Positive/Negative Predictive Values, Positive/Negative Likelihoodratios for pneumonia (for ultrasound parameters alone and within a clinical prediction score/decision tree) assessed by lung ultrasound (flow measured by color doppler imaging

and the dynamic air bronchogram). Pneumonia will be defined as the clinical diagnosis established by the treating physician when all clinical data necessary to establish a diagnosis are available (cq. CRP, leukocytes, Temperature, physical examination, Imaging summary (CXR or CT) and gram stain information). The timepoint for this diagnosis will be set at within 24 hours after the gramstain is available. The ultrasound will be performed within 24 hours of chest X-ray and the ultrasound diagnosis will be made directly at the bedside after completion of the ultrasound exam without delay.

Secondary outcome

Comparison of clinical prediction score based on clinical and ultrasound parameters for pneumonia and correlation with PF-ratio expressed as Sensitivity, Specificity, Positive/Negative Predictive Values, Positive/Negative Likelhoodratios and ICC. The exact same timeline in regards to measurement methods and timepoints will be used as for the primary outcome.

Study description

Background summary

The study will be a prospective, observational cohort study, conducted on the ICU of the Amsterdam UMC, Vrije Universiteit Amsterdam, a tertiary academic hospital in Amsterdam, the Netherlands. Patients will followed–up until discharge. The protocol was approved by the local ethics board as part of other ongoing studies and informed consent will be obtained by patients or their next of kin. STROBE-Guidelines (STrengthening the Reporting of OBservational studies in Epidemiology) will be followed.

Study population
The study population will consist of adult (>18 years) patients, admitted to the ICU, with any type of consolidation seen on chest X-ray (CXR). Patient with ARDS, trauma with pulmonary contusion and in contact isolation will be excluded. Sex, age, reason for ICU admission, SOFA score (Sequential Organ Failure Assessment) on the day of measurement, use of mechanical ventilation and inflammatory markers will be recorded on the same day of ultrasound assessment. Gram stain colouring and bacterial culture results will be recorded when made available in the electronic patient dossier.

Ultrasound Measurements:
All images will be made by an independent researcher, with a Philips CX50 ultrasound. All measurements will be performed following the BLUE-protocol, with additional measurements in the PLAPS point (see below). Image acquisition will take place directly after performance of the CXR, with a maximum duration of 24 hours between CXR and ultrasonographic examination. Evaluation of the images will take place directly after acquisition. Researchers making the images and measurements will blinded to the clinical status of the patient, and will only be allowed to view the chest X-ray.

Flow:
Pulmonary vascular flow will be assessed with color doppler. In order to maximize the sensitivity for low-velocity flow, the velocity scale will be set to 0.25m/sec. To avoid interference with adjacent structures, the window of assessment will be minimalized. Flow will be deemed present if homogeneously distributed tree-like, tortuous or fragmented vascular structures with blood flow in the lumen is seen through several respiratory cycles. In the case that flow is only seen in one part of the consolidation or only on one of the two PLAPS points, it is still denoted as being present.

Bronchogram:
Bronchograms will be assessed in B-mode with ultrasound settings to the preference of the researcher. They are defined as small punctiform or linear hyperechoic artefacts within the consolidated tissue. In case motion is visible in concordance with the patient's respiratory cycle it will be deemed dynamic.

Study objective

Advanced lung utltrasound, c.q. color doppler imaging and dynamic air bronchograms can aid in differentiating pneumonia from atelectasis

Study design

n.a.

Contacts

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Eligibility criteria

Inclusion criteria

Adult (18 years) patients admitted to the ICU with consolidation on chest X-ray

Exclusion criteria

ARDS, pulmonary contusion, contact isolation, COVID-19

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2018
Enrollment:	118
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
Upon reasonable request by other researchers for research purposes only

Ethics review

Positive opinion

Date:	15-12-2020
Application type:	First submission

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
NTR-new	NL9186
Other	METC VUmc : 2016.456

Study results