Novel Measurement Methodology for Diaphragm Ultrasound

No registrations found.

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

Summary

ID

NL-OMON23936

Source
NTR

Brief title
NOVUS

Health condition

Diaphragm dysfunction

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Feasibility expressed as image obtained yes/no, diaphragm excursion in millimetres measured from the PLAPS and subcostal view, ICC for excursion measured from both points

Secondary outcome

ICC for excursion measured from both points for different breathing patterns (quiet breathing, deep breathing, sniffing)

Study description

Background summary

Ultrasound has become a widely used tool on the Intensive Care Unit over the last decade. It's areas for application have since then expanded now also including imaging of the diaphragm and other respiratory muscles to for example, detect patient ventilator asynchrony, quantify its function and predict the outcome of extubation. However, the standard view for detecting diaphragm excursion (subcostal view) is often blocked by air in the stomach and/or intestines. For this reason, an alternative method to visualise excursion would be of interest. In this regard, the PLAPS-point (posters lateral alveolar and pleural syndrome point) presents itself as feasible alternative, given that the liver and spleen serve as acoustic windows to visualise the diaphragm and that it is already a standard point of evaluation for pulmonary pathology. We hypothesise that measurements from the PLAPS will be more feasible than from the subcostal view and yield a good ICC (> 0.8).

Measurements:
Two ultrasound devices will be used simultaneously to directly compare measurements made in the different measurement sites (subcostal and PLAPS). The subcostal excursion will be recorded in M-mode on midclavicular line as closely aligned to the movement of the dome as possible. The excursion in the PLAPS will be recorded in B-mode at the site of maximal excursion.

In order to test various clinical situations, measurements will be done during quiet breathing, short nasal breathing (sniffing) and deep breathing. The measurements will be repeated on both sides of the body.

This results in a total of 288 images (12 participants x2 transducers x2 sides x3 breathing patterns)

Study objective

Diaphragm excursion measured from the PLAPS point is more feasible than from the subcostal view and yields comparable results of excursion

Study design

Measurements will be performed using a Philips CX 50 machine and a Sonosite Edge II machine. Measurements will be taken once the volunteer is instructed and has performed the various breathing patterns.

Intervention

Ultrasound examination from the PLAPS and subcostal view

Contacts

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Eligibility criteria

Inclusion criteria

Healthy volunteers

Exclusion criteria

Unable to complete full ultrasonographic exam

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-03-2021
Enrollment:	12
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
Data will only be shared upon reasonable request by other researchers for research purposes only

Ethics review

Positive opinion

Date:	09-03-2021
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	NL9431

Register	ID
Other	METC VUmc : 2019.577

Study results