EffeCt of lung ultrasOuNd-guided Fluid deresuscItation on Duration of vEntilation iN intensive Care unit patiEnts (CONFIDENCE-trial)

Published: 29-11-2021
Last updated: 05-04-2024

LUS-guided fluid deresuscitation is superior to standard fluid deresuscitation without LUS with regard to duration of invasive ventilation

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54414

Source
ToetsingOnline

Brief title
CONFIDENCE

Condition

- Other condition

Synonym
mechanical ventilation, respiratory failure

Health condition

respiratory failure

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Deresuscitation, Intensive Care, mechanical ventilation, Ultrasound

Outcome measures

Primary outcome

Number of ventilator-free days and alive at day 28 (*VFD-28*)

Secondary outcome

ICU- and hospital length of stay; ICU-, hospital- and 90-day mortality;

cumulative fluid balance at successive days; proportion of patients who develop

kidney injury or atrial fibrillation.

Study description

Background summary

Timely recognition of pulmonary edema will lead to earlier extubation in intensive care unit (ICU) patients. Lung ultrasound (LUS) is a simple, safe non-invasive bedside imaging tool with high accuracy for pulmonary edema in ICU patients. We propose a study testing the effect of LUS-guided fluid deresuscitation on duration of invasive ventilation.

Study objective

LUS-guided fluid deresuscitation is superior to standard fluid deresuscitation without LUS with regard to duration of invasive ventilation

Study design

Multicenter randomized clinical trial

Intervention

LUS-guided fluid deresuscitation; decisions on start and speed of fluid deresuscitation are guided by LUS findings.

Study burden and risks

minimal, lung ultrasound is a non-invasive and painless investigation

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 one of the participating ICUs; and
- expected to be under invasive ventilation for longer than 24 hours

Exclusion criteria

(a) age < 18 years;
(b) pregnancy;
(c) participation in other interventional trials with similar endpoints;
(d) conditions in which LUS cannot be performed or correctly interpreted, i.e., chest abnormalities, morbid obesity, and pre-existing interstitial lung disease,
(e) previous participation in this RCT
(f) patients transferred from another center and invasively ventilated for longer than than 24 hours

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-12-2021
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	29-11-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	21-04-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	14-04-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL76936.018.21