Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of movement and thickness of diaphragm measured by ultrasound on weaning success in patients admitted to Intensive Care Unit

Protocol summary

Study aim

The main goal of this study is to evaluate the effect of diaphragmatic ultrasonography on the success of extubation (weaning from mechanical ventilation) in patients admitted to the Intensive Care Unit.

Design

This study is designed as a double-blinded randomized clinical trial. 60 mechanically ventilated respiratory ICU patients who meet the inclusion criteria will be randomly allocated into two groups of 30 (intervention and control groups). In the intervention group, in addition to usual methods, diaphragmatic ultrasonography will also be performed.

Settings and conduct

60 mechanically ventilated respiratory ICU patients who meet the inclusion criteria will be randomly allocated into two groups of 30 (intervention and control groups). In the intervention group, in addition to usual methods, diaphragmatic ultrasonography will also be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years Admitted to ICU due to respiratory failure under mechanical ventilation exclusion criteria: Having neuromuscular disease Presence of pleural effusion Decreased level of consciousness

Intervention groups

The intervention group includes 30 eligible patients who are randomly selected. In addition to standard methods for assessing readiness for extubation (e.g. RSBI index), patients in the intervention group undergo diaphragmatic ultrasonography performed by the study investigator (anesthesia resident). In the diaphragmatic ultrasound, the movement and thickness of the diaphragm are measured in M-mode. The findings from the diaphragmatic ultrasound serve as the basis for deciding whether the patient is ready for extubation.

Main outcome variables

Main outcome measures including rates of successful extubation, duration of extubation and ICU length of stay will be compared between the two groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190215042716N5**
Registration date: **2023-12-20, 1402/09/29**
Registration timing: **prospective**

Last update: **2023-12-20, 1402/09/29**
Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

navid shafigh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 3378

Email address

n.shafigh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of movement and thickness of diaphragm measured by ultrasound on weaning success in patients admitted to Intensive Care Unit

Public title
Evaluation of movement and thickness of diaphragm measured by ultrasound on weaning success in patients admitted to Intensive Care Unit
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Admitted to ICU due to respiratory failure Under mechanical ventilation Meeting the extubation criteria
Exclusion criteria:
Having neuromuscular disease Presence of pleural effusion Decreased level of consciousness
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After initial screening and selecting 60 eligible patients based on the inclusion and exclusion criteria, their baseline and demographic information will be recorded. The APACHE II and SOFA scores of the patients will be calculated to determine the severity of their illness. The patients will be compared in terms of illness severity, and 30 patients with similar severity will be placed in group A and 30 other patients with similar severity in group B. Then, using a random number generation software, group A will be selected as the intervention group and group B as the control group. This is how patients will be randomly allocated to the two 30-people intervention and control groups. Finally, the intervention will be applied to the intervention group and the results will be compared with the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is designed as a double-blinded randomized clinical trial. This means that not only are the patients unaware of their allocation to either the intervention or control group, but the treating physicians and nurses are also blinded to the patient allocation .Therefore, neither the patient nor the treating physician/nurse know which group the patient is allocated to. This is done to eliminate bias in the results.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences and Health Services
Street address
SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2023-11-22, 1402/09/01
Ethics committee reference number
IR.SBMU.MSP.REC.1402.343

Health conditions studied

1

Description of health condition studied
weaning of mechanical ventilation
ICD-10 code
T88.4
ICD-10 code description
Failed or difficult intubation

Primary outcomes

1

Description
Main outcome measures including rates of successful extubation, duration of extubation and ICU length of stay will be compared between the two groups.
Timepoint
one weak
Method of measurement
sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group includes 30 eligible patients who are randomly selected. In addition to standard methods for assessing readiness for extubation (e.g. RSBI index), patients in the intervention group undergo diaphragmatic ultrasonography performed by the study investigator (anesthesia resident). In the diaphragmatic ultrasound, the movement and thickness of the diaphragm are measured in M-mode. The findings from the diaphragmatic ultrasound serve as the basis for deciding whether the patient is ready for extubation

Category
Treatment - Devices

2

Description
Control group: The control group contains 30 patients similar to the intervention group in terms of demographic characteristics and illness severity, selected randomly. In this group, patients receive standard existing care in the ICU and diaphragmatic ultrasonography is not performed. The criteria for deciding on extubation is also based on standard methods.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Labbafinezhad Hospital

Full name of responsible person
Navid shafigh

Street address
9th Boostan, Pasdaran St.

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1956944413

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Lamc@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Navid Shafigh

Street address
Shahid Shahriari Square, Daneshjo Boulevard, Shahid Chamran Highway,

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Navid Shafigh

Position
Consultant

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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N0.15, 26 Ave ,27 Ave, Kordestan Blvd , Tehran Yown

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The whole potential data after being unidentifiable is published

When the data will become available and for how long
One year

To whom data/document is available
Medical Society

Under which criteria data/document could be used
Letter from the studied university

From where data/document is obtainable
Email: n.shafigh@sbmu.ac.ir

What processes are involved for a request to access data/document
Registration of applications and letters from the university and review and presentation of information within one month

Comments