

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of respiratory muscle exercises on pulmonary functional indices and successful extubation in patients hospitalized in the intensive care unit."

Protocol summary

Study aim

Determining the effect of respiratory muscle training on lung function indicators and success of extubation in patients hospitalized in the intensive care unit

Design

The present study is a controlled clinical trial. Patients are randomly assigned to intervention and control groups. The sample size in each group will be calculated as a pilot. Samples with entry criteria are selected in the available method, and then permutation blocks with size 4 and 2 will be produced by a statistician with the help of Stata software version 17. To hide the allocation of each block, it will be placed in an envelope. After completing each sampling with the envelope, the envelope is discarded and the next envelope will be opened.

Settings and conduct

Special care departments of Imam Reza Hospital in Mashhad

Participants/Inclusion and exclusion criteria

Entry criteria: more than 48 hours under mechanical ventilation, GCS \geq 13, PI max \leq -20 cmH₂O, PaO₂ > 60, PaO₂/FiO₂ \geq 200, SPO₂ > 90, TV > 5 ml/kg, RR < 35, RSBI < 135 lit/min, no fever and stable hemodynamic status. Exclusion criteria: inability to perform breathing exercises, unstable hemodynamic status of the patient, presence of barotrauma, need to use sedative or muscle relaxant during intervention, history of neuromuscular disease

Intervention groups

In both groups, routine exercises including chest physiotherapy will be performed by a physiotherapist once a day. In the intervention group, in addition to routine exercises, respiratory muscle strengthening exercises using the Threshold IMT/PEP device, twice a day for one week, include: tail muscle exercises In 5 sets of 10 breaths with an intensity of 40% of P_Imax and exhalation exercises with PEP: 7 cm H₂O will be done for

half an hour.

Main outcome variables

RSBI; MIP; MEP; pulmonary compliance; Diaphragm thickness; Extubation success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230214057418N1**

Registration date: **2023-04-14, 1402/01/25**

Registration timing: **prospective**

Last update: **2023-04-14, 1402/01/25**

Update count: **0**

Registration date

2023-04-14, 1402/01/25

Registrant information

Name

Mohammad Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-10, 1402/02/20

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of respiratory muscle exercises on pulmonary functional indices and successful extubation in patients hospitalized in the intensive care unit."

Public title
The effect of breathing training on lung function and extubation

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
be under mechanical ventilation for more than 48 hours
GCS \geq 13 PI max \leq -20 cmH₂O PaO₂>60 PaO₂/FiO₂ \geq 200 SPO₂>90 TV > 5 ml/kg RR<35 RSBI < 105 lit/min no fever stable in hemodynamic status age between 18-80 years old
Exclusion criteria:
A history of neuromuscular disease that may affect respiratory muscle function.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples meeting the inclusion criteria will be selected, and then permuted blocks of size 4 and 2 will be generated using Stata software version 17 by a statistician. To conceal the allocation of each block, they will be placed in a packet.

Blinding (investigator's opinion)
Single blinded

Blinding description
The method of closed envelopes is used to allocate patients to groups. In this way, the generated random sequences are kept in closed envelopes. When a patient with inclusion criteria is found, the envelope is opened to identify his group. The outcome assessor and the statistics professor will also be unaware of this allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah Ave, Ghoeshi Building

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2023-03-14, 1401/12/23

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.123

Health conditions studied

1

Description of health condition studied

Weakness of respiratory muscles in patients under mechanical ventilation.

ICD-10 code

Z99.11

ICD-10 code description

Dependence on respirator [ventilator] status

Primary outcomes

1

Description

pulmonary functional indices

Timepoint

Every day before and after the intervention

Method of measurement

Ventilator

2

Description

successful extubation

Timepoint

48 hours after extubation

Method of measurement

Clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Control group: Routine exercises include chest physiotherapy (Vibration & Percussion, etc.) in the form of creating passive movement in the organs, compression and percussion in the chest, compressive stretching and vibration on the chest and changing the position, which is done by the physiotherapist. It is performed once a day for an average of 15 minutes, the intensity of which will vary based on the patient's cooperation and vital signs.

Category

Treatment - Devices

2

Description

Intervention group: Intervention group: in the test group, in addition to physical therapy routine exercises, inspiratory and expiratory muscle strengthening exercises will be added by the Threshold IMT/PEP device that is connected to the end of the tracheal tube. Respiratory muscle exercises twice a day for one week include: inspiratory muscle exercises under the supervision of the researcher in 5 sets of 10 breaths with an intensity of 40% of P_{Imax} and expiratory exercises with PEP: 7 cm H₂O for half an hour.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Razieh Froutan

Street address

Ibn Sina Street, Imam Reza Hospital Square, Imam Reza Educational Research and Treatment Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Kazemi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available