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 ≥ 13, PI max ≤ -20 cmH2O, PaO2 > 60, PaO2/FiO2 ≥ 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 PImax 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)

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+98 51 3211 9640

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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 ≥ 13 PI max ≤ -20 cmH2O PaO2>60 PaO2/FiO2 ≥ 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, Ghoeishi Building

City

Mashhad

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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 PImax 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

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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

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Mashhad University of Medical Sciences

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Position
Associate Professor of Nursing

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Person responsible for updating data

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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