Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of inspiratory muscle training with common chest physiotherapy on the weaning duration in patients hospitalized in intensive care units

Protocol summary

Study aim

The effect of adding muscle strengthening exercises by Threshold IMT to the physiotherapy and regular exercises on the strength of respiratory muscles and weaning time

Design

Clinical trial with control group, with parallel groups, one-way blinding, random assignment using closed-envelope method.

Settings and conduct

The present clinical trial will be performed on eligible patients admitted to the intensive care units of Imam Reza Hospital in Mashhad. In the intervention group, in addition to routine chest physiotherapy, daily muscle training exercises are performed in 5 series of 6 breaths with an intensity of 50% of maximal inspiratory pressure (MIP) for one week. In the control group, only routine chest physiotherapy will be performed. Participants (patients) are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Be hospitalized in the intensive care unit. Be connected to a ventilator for at least 24 hours. Be stable in hemodynamic status (Blood Pressure. Pulse Rate. Respiratory Rate, O2). Positive end-expiratory pressure (Peep) <10 cmH2O. Fractional Inspired Oxygen (FIO2) < 0.60%. Respiratory rate <25. Exclusion criteria: It is not possible to continue muscle training exercises, for any reason. The patient's hemodynamic status becomes unstable.

Intervention groups

In the intervention group, in addition to routine chest physiotherapy, daily muscle training exercises are performed in 5 series of 6 breaths with an intensity of 50% of maximal inspiratory pressure (MIP) for one week. In the control group, only routine chest physiotherapy will be performed.

Main outcome variables

Strength of inspiratory muscles. Duration of ventilator weaning.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200915048728N1**
Registration date: **2021-02-28, 1399/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-28, 1399/12/10**
Update count: **0**

Registration date

2021-02-28, 1399/12/10

Registrant information

Name

Farnoosh Khodabandeloo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3881 4241

Email address

f.khodabandeloo@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of inspiratory muscle training with common chest physiotherapy on the weaning duration in patients hospitalized in intensive care units

Public title
Comparison of the effect of inspiratory muscle training with common chest physiotherapy on the weaning duration in patients hospitalized in intensive care units

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Be hospitalized in the intensive care unit. Be connected to a ventilator for at least 24 hours Be stable in hemodynamic status (Blood Pressure. Pulse Rate .Respiratory Rate, O2) Positive end-expiratory pressure (Peep) <10 cmH2O Fractional Inspired Oxygen (FIO2) < 0.60% Respiratory rate <25/per minute
Exclusion criteria:
It is not possible to continue muscle training exercises, for any reason. The patient's hemodynamic status becomes unstable

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
The closed-envelope method is used. Random sequences generated are stored in these closed envelopes. After selecting the new eligible patient, the envelope is opened to determine his group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants (patients) are blinded.

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
Ghoreyshi building, Daneshgah street.
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199

Approval date
2020-08-18, 1399/05/28

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.350

Health conditions studied

1

Description of health condition studied
patients under mechanical ventilation

ICD-10 code
Z99.11

ICD-10 code description
Dependence on respirator [ventilator] status

Primary outcomes

1

Description
Strength and endurance of respiratory muscle

Timepoint
Respiratory muscle strength before and after Inspiratory muscle training

Method of measurement
Measurement of inspiratory muscle strength by mechanical ventilator

2

Description
Duration of patient weaning from ventilator

Timepoint
At the beginning of the study, one week after starting the exercises and then every day

Method of measurement
Time to wean from the ventilator based on hour

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine chest physiotherapy, daily inspiratory muscle training will be performed in 5 series of 6 breaths with an intensity of 50% of maximal inspiratory pressure for one week.

Category

Rehabilitation

2

Description

Control group: They will only receive routine chest physiotherapy.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Farnoosh Khodabandeloo

Street address

School of medicine, Bahonar Ave, Vakilabad Blvd.

City

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Email

f.khodabandeloo@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreishi building, Daneshgah Street.

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vcresearch@mums.ac.ir

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

Ahmad Bagheri Moghaddam

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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School of medicine, Bahonar Ave, Vakilabad Blvd.

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Email

bagheria@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farnoosh Khodabandeloo

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Farnoosh Khodabandeloo

Position

student

Latest degree

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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

Not applicable