

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The impact of early initiation of inspiratory muscle training (IMT) on pulmonary function and sleep quality in patients with asthma attack: a randomized clinical trial study.

Protocol summary

Study aim

To determine the effect of early initiation of inspiratory muscle training on pulmonary function in patients with acute asthma attacks.

Design

A phase 2-3 randomized controlled clinical trial with parallel groups and a single-blind design will be conducted on 102 patients. Randomization will be performed using the Sealed Envelope website (sealedenvelope.com).

Settings and conduct

This randomized clinical trial will be conducted at Shahid Jalil Hospital, Yasuj, on patients with acute asthma. Participants will be randomly allocated using Sealed Envelope into intervention and control groups. The intervention group will receive 6 weeks of IMT, while the control group receives standard care. Pulmonary function and sleep quality will be assessed at baseline and at the end of the study. The study is single-blind, with blinded outcome assessors and data analysts.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with acute asthma attacks with at least three months since diagnosis, no long-term use of continuous positive airway pressure (CPAP) or similar positive pressure ventilation devices, and no history of stroke. Exclusion criteria: Presence of lung cancer or other end-stage malignancies.

Intervention groups

In the intervention group, patients will undergo inspiratory muscle training using the IMT K5 POWERbreathe device for 6 weeks (two sessions per week). The intervention will begin 5-7 days after clinical stabilization. Training intensity will be individually set at 30% of baseline inspiratory pressure and adjusted progressively based on each patient's tolerance. The control group will receive standard routine hospital care only. At the end of the intervention, all baseline

assessments and questionnaires will be repeated in both groups.

Main outcome variables

Pulmonary function: Sleep Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260423069136N1**

Registration date: **2026-05-13, 1405/02/23**

Registration timing: **prospective**

Last update: **2026-05-13, 1405/02/23**

Update count: **0**

Registration date

2026-05-13, 1405/02/23

Registrant information

Name

Pegah Mohammad-zadeh Shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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mohammadzadeh.sh6@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-05, 1405/03/15

Expected recruitment end date

2026-08-06, 1405/05/15

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The impact of early initiation of inspiratory muscle training (IMT) on pulmonary function and sleep quality in patients with asthma attack: a randomized clinical trial study.

Public title

Early Inspiratory Muscle Training (IMT) on Lung Function and Sleep in Acute Asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Asthma attack exacerbation No long-term use of continuous positive airway pressure (CPAP)

Exclusion criteria:

Presence of lung cancer or other end-stage malignancies

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated using block randomization to ensure balanced group sizes. Group A is the intervention, and Group B is the control. The allocation sequence will be generated randomly using the Sealed Envelope website, and participants will be assigned accordingly. To minimize predictability, variable block sizes (2, 4, 6, and 8) will be used.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is designed as a single-blind trial. Participants will be aware of the intervention they receive; however, the outcome assessor and the data analyst will be blinded to group allocation and the type of intervention administered. This approach is intended to reduce assessment and analytical bias and to enhance the validity of the study findings, while full blinding of participants is not feasible due to the nature of the intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Daneshgah St., Motahari Blvd., Jahad Town

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Province

Kohgiluyeh-va-Boyerahmad

Postal code

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Approval date

2025-11-19, 1404/08/28

Ethics committee reference number

IR.YUMS.REC.1404.175

Health conditions studied

1

Description of health condition studied

Asthma Attack

ICD-10 code

J45.901

ICD-10 code description

Unspecified asthma with (acute) exacerbation

Primary outcomes

1

Description

Pulmonary function

Timepoint

Before and immediately after the end of the intervention

Method of measurement

Pulmonary spirometry (using the Spiromax device manufactured by Teb Tasvir Company)

2

Description

Sleep Quality

Timepoint

Before and immediately after the end of the intervention

Method of measurement

Use of the Pittsburgh Sleep Quality Index (PSQI) questionnaire

Secondary outcomes

1

Description

Dyspnea severity

Timepoint

Before and immediately after the end of the intervention.

Method of measurement

Rating of Perceived Exertion (RPE)

Intervention groups

1

Description

Intervention group: Patients will receive inspiratory muscle training (IMT) using the IMT K5 POWERbreathe device for 6 weeks, with two sessions per week. Training intensity will initially be set at 30% of each patient's baseline inspiratory pressure and progressively increased according to tolerance.

Category

Treatment - Devices

2

Description

Control group: Patients will receive standard routine care without IMT intervention.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Jalil Hospital

Full name of responsible person

Hossein Hejr

Street address

Imam reza St., Gharani Blvd., Imim Hossein Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Sirous Saleh-nasab

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Sajjad Hassan-zadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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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

Not applicable

Title and more details about the data/document

After the completion of the study, all study data will be shared after being de-identified

When the data will become available and for how long

The Commencement Of The Access Period Is 3 Months After The Publication Of The Results

To whom data/document is available

The study data will be available to academic and scientific researchers working in medical sciences centers.

Under which criteria data/document could be used

Individuals associated with the medical and therapeutic fields may utilize the data from this study to conduct new research.

From where data/document is obtainable

Via official email to the corresponding author at: sajad.hassanzadeh@gmail.com.

What processes are involved for a request to access data/document

The applicant must submit their formal request via the organization's email to the responsible author's email address. The accountable author will provide the information to the applicant within a maximum of two weeks after they confirm the information

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

Sajjad Hassan-zadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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