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 functioy: 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
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Iran (Islamic Republic of)
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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

Kohgilouyeh-va-Boyrahmad

Postal code

7591875111

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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