

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of lip bud and diaphragm breathing versus control group on the comfort and pulmonary function of chronic obstructive pulmonary disease patients: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of lip bud and diaphragm breathing versus control group on the comfort and pulmonary function of COPD patients

##### Design

This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the drawing of lots to the interventions and control groups

##### Settings and conduct

This study will be performed in the Imam Hossain Hospital in Malayer city on 141 eligible patients with COPD. The patients will be randomly assigned to the intervention and control groups through the drawing of lots/. Blinding is not possible in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 75 years Chronic obstructive pulmonary disease Hemoglobin at least 11 g/dL Temperature 36.5 to 37.5 Systolic blood pressure at least 100 mmHg Exclusion criteria: Receiving supportive oxygen in the past 6 hours Heart, kidney or liver failure Diabetes Uncontrolled hypertension

##### Intervention groups

Intervention group 1: Routine treatment in addition to diaphragm breathing for 10 minutes, three times daily for 4 weeks Intervention group 2: Routine treatment plus lip bud breathing for 10 minutes, three times daily for 4 week Control group: Only routine treatment

##### Main outcome variables

Primary outcome: Breathing rate, oxygen saturation (SPO2), forced expiratory air pressure in the first second (FEV1), patient comfort

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20120215009014N476**

Registration date: **2023-07-12, 1402/04/21**

Registration timing: **prospective**

Last update: **2023-07-12, 1402/04/21**

Update count: **0**

#### Registration date

2023-07-12, 1402/04/21

#### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

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#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-07-23, 1402/05/01

#### Expected recruitment end date

2023-12-22, 1402/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of lip bud and diaphragm breathing versus control group on the comfort and pulmonary function of chronic obstructive pulmonary disease patients: a randomized clinical trial

#### Public title

Effect of lip bud and diaphragm breathing versus control group on the comfort and pulmonary function of chronic obstructive pulmonary disease patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age 18 to 75 years Chronic obstructive pulmonary disease Hemoglobin at least 11 g/dL Temperature 36.5 to 37.5 Systolic blood pressure at least 100 mmHg

##### Exclusion criteria:

Receiving supportive oxygen in the past 6 hours Heart, kidney or liver failure Diabetes Uncontrolled hypertension

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **141**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare three sheets and write "intervention 1" on one sheet and "intervention 2" on the second and "control" on the third one. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the interventions or control group.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

#### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2023-06-10, 1402/03/20

#### Ethics committee reference number

IR.UMSHA.REC.1402.241

## Health conditions studied

### 1

#### Description of health condition studied

Chronic obstructive pulmonary disease

#### ICD-10 code

J44

#### ICD-10 code description

Other chronic obstructive pulmonary disease

## Primary outcomes

### 1

#### Description

Breathing rate

#### Timepoint

Before the intervention and 4 weeks after the intervention

#### Method of measurement

By clinical examination

### 2

#### Description

Oxygen saturation (SPO2)

#### Timepoint

Before the intervention and 4 weeks after the intervention

#### Method of measurement

Using pulse oximeter

### 3

#### Description

Forced expiratory air pressure in the first second (FEV1)

#### Timepoint

Before the intervention and 4 weeks after the intervention

#### Method of measurement

Using a spirometer

### 4

#### Description

Patient comfort

**Timepoint**

Before intervention and 4 weeks after intervention

**Method of measurement**

Using visual analog scale (VAS)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group 1: Routine treatment in addition to diaphragm breathing (the patient lies on the bed and puts a pillow under his head and knees. He puts one hand on his chest and the other hand on his abdomen. When breathing, the hand on the stomach moves upwards and during exhalation, the hand moves down on the stomach, while the other hand remains motionless on the chest during inhalation and exhalation. Inhalation should be through the nose and exhalation through the mouth) for 10 minutes, three times daily for 4 weeks

**Category**

Other

**2****Description**

Intervention group 2: Routine treatment plus lip bud breathing (the patient closes his mouth and takes a deep breath through his nose, then exhales while keeping his lips pursed (whistling or kissing) ) for 10 minutes, three times daily for 4 week

**Category**

Treatment - Other

**3****Description**

Control group: Only routine treatment

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hossain Hospital in Malayer city

**Full name of responsible person**

Leila Zand Hajiabadi

**Street address**

Imam Hussein Hospital, Parastar Boulevard, Azad University Ave. Park Ave.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Leila Zand Hajiabadi

**Position**

Student of Special Cares

**Latest degree**

Master

**Other areas of specialty/work**

Emergency Medicine

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**Person responsible for scientific inquiries**

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**Position**

PhD in Nursery

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Ph.D.

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**Person responsible for updating data**

**Contact**

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Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

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Epidemiology

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available