

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

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Iran (Islamic Republic of)

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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

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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

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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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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 updating data

Contact

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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