Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Name of organization / entity
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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
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
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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
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Position
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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