Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of motivational spirometry and diaphragmatic breathing on arterial blood oxygen saturation in patients with COVID hospitalized

Protocol summary

Study aim

compare the effect of diaphragmatic breathing and motivational spirometry on blood oxygen saturation (SpO_2) in patients with COVID-19.

Design

An open-label, parallel, randomized clinical trial with 2 active intervention groups will be conducted on 80 COVID-19 patients at Sina Hospital, Tehran. The sample size will be calculated based on a previous study and allocated at a 1:1 ratio; the study will not have a clinical phase.

Settings and conduct

This study will be conducted in the COVID-19 ward of Sina Hospital, Tehran. 80 conscious COVID-19 patients will be divided into two groups of 40 and will receive a respiratory intervention session consisting of 3 sets of 10 breaths with 30 seconds of rest. SpO_2 and vital signs will be measured before, immediately, 5 and 10 minutes after the intervention. The study was open-label and only the statistical analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: COVID-19 patients with a confirmed diagnosis, conscious and cooperative, ≤50% lung involvement, physician prescription for respiratory physiotherapy, normal blood pressure and heart rate, no COPD/bronchospasm, no medications affecting vitals, and no need for invasive ventilation. Exclusion criteria: Instability of vital signs or level of consciousness, occurrence of complications during the intervention, or patient unwillingness to continue cooperation.

Intervention groups

Diaphragmatic breathing group: Deep breathing focusing on diaphragm movement Incentive spirometry group: Using an incentive spirometer with deep, slow breathing to achieve maximum inspiratory volume, then slow exhalation

Main outcome variables

SpO_2 changes at four time points: baseline, immediately, 5 and 10 minutes after intervention; analysis with repeated measures ANOVA and Greenhouse-Geisser correction in both groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251118068029N1**
Registration date: **2025-11-20, 1404/08/29**
Registration timing: **prospective**

Last update: **2025-11-20, 1404/08/29**
Update count: **0**

Registration date

2025-11-20, 1404/08/29

Registrant information

Name

Ali Karimirozveh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

karimi_rozveh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-22, 1404/09/01

Expected recruitment end date

2026-01-17, 1404/10/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of motivational spirometry and diaphragmatic breathing on arterial blood oxygen saturation in patients with COVID hospitalized

Public title

Studying the effect of motivational spirometry and diaphragmatic breathing on arterial blood oxygen saturation.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious and cooperative individuals Having a definite diagnosis of COVID-19 Maximum 50% lung involvement Requiring a physician’s order for respiratory physiotherapy Systolic and diastolic blood pressure ranged 100-140 mmHg and 60-90 mmHg, respectively Heart rate range of 60-100 beats per minute

Exclusion criteria:

Suffering from COPD or bronchospasm (based on medical reports confirmed by a specialist) Being under the prescription of drugs that control vital signs (e.g., dopamine, dobutamine, nitroglycerin) Need of invasive ventilation

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after selecting the samples using a convenience method, participants will be assigned to two intervention groups (diaphragmatic breathing and motivational spirometry) in a 1:1 ratio using a computer-generated random number table. This process will be performed without researcher intervention and according to standard randomization principles.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The study will be conducted as a randomized clinical trial with a parallel design. Due to the nature of the intervention, it was not possible to blind participants and administrators, but the statistical analyst will be blinded. Group allocation will be done with a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences - Faculty of Nursing and Midwifer

Street address

Somayeh St

City

Tehran

Province

Tehran

Postal code

1581749811

Approval date

2022-04-27, 1401/02/07

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.102

Health conditions studied

1

Description of health condition studied

Coronavirus disease (COVID-19)Respiratory hypoxia in patients with COVID-19 (with up to 50% lung involvement and no need for invasive ventilation)

ICD-10 code

B97.2

ICD-10 code description

Coronavirus as the cause of diseases classified to other chapters

Primary outcomes

1

Description

Changes in arterial oxygen saturation (SpO_2) measured with a calibrated pulse oximeter at four times: before the intervention, immediately after the intervention, 5 minutes after the intervention, and 10 minutes after the intervention.

Timepoint

Time points for measuring the main outcome (SpO_2 and other vital signs):Before the intervention (Baseline)Immediately after the end of the intervention5 minutes after the end of the intervention10 minutes after the end of the intervention

Method of measurement

The percentage of arterial oxygen saturation (SpO_2) will be measured non-invasively from the index or middle

finger of the patient's non-dominant hand using a Saadat digital pulse oximeter device that has been calibrated and validated by the hospital's medical engineers. The measurement will be performed at four time points (before the intervention, immediately after, 5 minutes after, and 10 minutes after the intervention) and under the same conditions (sitting/semi-sitting position and complete patient rest), and the values will be recorded directly from the ward's central monitor and pulse oximeter.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Diaphragmatic breathing: The patient, in a sitting or semi-sitting position, places one hand on the chest and the other on the abdomen. Deep breathing is performed through the nose so that only the hand on the abdomen rises (the chest remains fixed), then with pursed-lips and gentle pressure on the abdomen, slow exhalation is performed (exhalation time is twice the inhalation time). The intervention will be performed in three periods of 10 breaths (rate of 10 breaths per minute) with a 30-second rest between periods.

Category
Rehabilitation

2

Description
Intervention group: Use of an incentive spirometry device (inspiratory type, Saadat Company, calibrated): The patient, in a sitting or semi-sitting position, after a complete exhalation, places the mouthpiece of the device completely in the mouth and takes a deep and slow breath to reach the maximum inspiratory volume with visual feedback from the device. After each inhalation, the mouthpiece is removed and a slow exhalation is performed (exhalation time is twice the inhalation time). The intervention will be performed exactly the same as the first group in three periods of 10 breaths with a 30-second rest between periods.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina hospital

Full name of responsible person
Ali Karimirozveh

Street address
Sina Hospital, Hassan Abad Square, Imam Khomeini Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1136746911

Phone
+98 21 6634 8500

Email
hosp_sina@sina.tums.ac.ir

Web page address
https://sinahospital.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Ramin Kordi

Street address
Office of the Vice President for Research and Technology, 6th Floor, Central University Organization, At the corner of Qods Street and Keshavarz Boulevard

City
Tehran

Province
Tehran

Postal code
141765383761

Phone
+98 21 8163 3698

Email
vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Ali Karimirozveh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Dr. Mirkhani St. (East Nusrat), Tawheed Square
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Email
karimi_rozveh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Karimirozveh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Dr. Mirkhani St. (East Nusrat), Tawheed Square
City
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Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Email
karimi_rozveh@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Karimirozveh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Dr. Mirkhani St. (East Nusrat), Tawheed Square
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karimi_rozveh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
The main data file includes 80 patients (40 in the diaphragmatic breathing group + 40 in the incentive spirometry group). The variables in the data are: Demographic characteristics (age, gender, education level, length of hospitalization, percentage of lung involvement, oxygen therapy method, underlying disease). Vital signs and SpO_2 at four time points (before the intervention, immediately after, 5 minutes later, 10 minutes later). Complications during the intervention (tachycardia, bradycardia, respiratory distress, decreased consciousness, etc.). Randomization code and patient group This file can also be shared, but perhaps only parts of it will be published publicly. We will probably only share the raw and more detailed data with others upon formal request and approval from the ethics committee, because participant confidentiality is a red line for us. In general, we would like our data and findings to be shared with the world, but with caution and care, to both advance science and preserve the privacy of the samples.
When the data will become available and for how long
Access begins 6 months after results are published.
To whom data/document is available
Researchers working in academic institutions and industry
Under which criteria data/document could be used
Our anonymized data is a treasure trove that we can

share with caution. Researchers can use this data for statistical analyses, such as comparing means or examining correlations, or use educational documentation to design similar courses. All of this will be under the supervision of an ethics committee and with a commitment to confidentiality. To request access, they must provide a formal letter stating the purpose of the research, ethical approval from a reputable institution, and a commitment not to publish the raw data so that we can safely share this information with them.

From where data/document is obtainable

To Dr. Ali Karimi Rozveh, faculty member of the project, email karimi_rozveh@yahoo.com

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

In order for the documents or data files to reach the applicant, there are a few simple but important steps that need to be taken. Your request is like a letter that first reaches Dr. Ali Karimi Rozveh, the study's director; simply submit it via email or by calling the Tehran University of Medical Sciences' School of Nursing and Midwifery. He or she will review your request, including the intended use and ethical documents, and if everything is complete, will give initial approval. This usually takes about a week. Next, the data must be anonymized; for example, student names and codes are removed to maintain privacy. This step, which is performed by the research team, takes about 5 to 7 days. Then, the Tehran University of Medical Sciences' Ethics Committee does a final review to make sure everything is in order. this also takes another week. Finally, the files will be sent to you via email or secure drive. Overall, if your application is complete and flawless, it will take about 2 to 3 weeks for this treasure to reach you.

Comments