Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of pursed lip breathing on arterial blood oxygen saturation in patients with COVID-19

Protocol summary

Study aim
Determining the effect of bud lip breathing on arterial blood oxygen saturation in people with COVID-19

Design
A clinical trial with a control group, with parallel groups, randomized, phase 2 on 70 patients, and random block method will be used.

Settings and conduct
Patients with COVID-19 referred to the Shahid Dr. Chamran hospital in Tehran city are selected by the convenience method and divided into two groups with Block randomization method. Then the results will be compared in the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: Being between 18 and 70 years old, the ability to do lip-bud breathing, Having Spo2 above 85%, breathing rate less than 40 times per minute, Positive PCR or lung involvement on CT scan. Exclusion criteria include: Heart rate less than 40 or more than 120 beats per minute, History of new cardiac arrhythmia or ischemia and Having hemoglobin less than 11 grams per deciliter.

Intervention groups
Intervention group: in this group, in addition to the usual treatments and care, the patients were taught face-to-face method, the lip bud breathing technique 2 times a day with an interval of 5 minutes and 10 times each time on the second, third and fourth days of hospitalization. Control group: This group receives only the usual treatments and care.

Main outcome variables
Arterial blood oxygen saturation, heart rate, duration of hospitalization, blood pressure, respiratory rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221124056590N1**
Registration date: **2022-12-17, 1401/09/26**
Registration timing: **prospective**

Last update: **2022-12-17, 1401/09/26**
Update count: **0**

Registration date
2022-12-17, 1401/09/26

Registrant information
Name
soheila yaghooby hamedan
Name of organization / entity
Shaheed Rajaie Cardiovascular, Medical & Research Center
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-01-21, 1401/11/01
Expected recruitment end date
2023-04-21, 1402/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of pursed lip breathing on arterial blood oxygen saturation in patients with COVID-19

Public title
The effect of pursed lip breathing on arterial blood oxygen saturation
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Being between 18 and 70 years old The ability to do lip-bud breathing Having Spo2 above 85% Breathing rate less than 40 times per minute Positive PCR or lung involvement on CT scan
Exclusion criteria:
Heart rate less than 40 or more than 120 beats per minute History of new cardiac arrhythmia or ischemia Having hemoglobin less than 11 grams per deciliter
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
First, a convenient sampling method will be used. The samples will then be placed in quadruple blocks by random block randomization. Random allocation software is also used as a randomization tool. Non-transparent envelopes will be used and will be sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes will be opened in order and the assigned group of the participants will be revealed.
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 Shahid Rajaei Cardiovascular Medical and Research Center
Street address
Rajaie Cardiovascular Medical and Research Center, next to Mellat Park,Vali Asr St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1995614331
Approval date
2022-11-05, 1401/08/14
Ethics committee reference number
IR.RHC.REC.1401.057

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Arterial blood oxygen saturation
Timepoint
Before the start of the intervention (second day of hospitalization) and on the fourth day of hospitalization
Method of measurement
Using a pulse oximeter

2

Description
Systolic and diastolic blood pressure
Timepoint
Before the start of the intervention (second day of hospitalization) and on the fourth day of hospitalization
Method of measurement
Using a sphygmomanometer

3

Description
Pulse Rate
Timepoint
Before the start of the intervention (second day of hospitalization) and on the fourth day of hospitalization
Method of measurement
Using a pulse oximeter

4

Description

Number of breaths per minute

Timepoint

Before the start of the intervention (second day of hospitalization) and on the fourth day of hospitalization

Method of measurement

By observing the number of chest movements per minute

5

Description

Length of hospitalization

Timepoint

At the time of discharge

Method of measurement

According to the number of days of hospitalization

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group, in addition to the usual treatments and care, the patients were taught face-to-face method, the lip bud breathing technique 2 times a day with an interval of 5 minutes and 10 times each time on the second, third and fourth days of hospitalization.

Category

Rehabilitation

2

Description

Control group: Control group: This group receives only the usual treatments and care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dr. Chamran Hospital

Full name of responsible person

Soheila Yaghoobi Hamadan

Street address

NO.17 ,Shahid Dr Chamran Hospital,Shahid fakhrizadeh Street, Langari Street, Nobonyad square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Dr. Fereidoon Noohi

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Rajaie Cardiovascular Medical and Research Center, next to Mellat Park, Vali Asr St., Tehran,Iran

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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

Rajaie Cardiovascular Medical and Research Center

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

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Soheila yaghoobi Hamadan

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact
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Full name of responsible person
Shima Hadipoorzadeh
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Assistant Professor of Cardiac Anesthesia
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Soheila Yaghoobi Hamadan
Position
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Latest degree
Master
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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