

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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)

Phone

+98 21 7679 1267

Email address

syaghooby35@gmail.com

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

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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
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Full name of responsible person
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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 updating data

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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