

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The combined effect of deep breathing and prone position on common respiratory symptoms in patients with COVID-19

Protocol summary

Study aim

Determining the combined effect of deep breathing and prone position on common respiratory symptoms in patients with COVID-19

Design

Clinical trial without control group, with parallel, randomized groups, 96 patients

Settings and conduct

Approval of the ethics committee. Complete the informed consent form. First, complete a checklist of demographic characteristics and measure the Dyspnea with the Visual Analog Scale and the Borg's Scale. Measurement of Blood oxygen saturation level using pulse oximetry and measurement of respiration and cough using a checklist prepared by the researcher. Then, immediately after the interventions, re-measure the Dyspnea using the analog visual scale and the Borg's Scale. The intervention site is the corona ward of Shahid Jalil Hospital in Yasuj.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Ability to communicate and answer questions 2- Satisfaction to participate in the study and sign the form of informed consent Inclusion criteria: 1- Patient dissatisfaction with the continuation of the study

Intervention groups

Deep Breathing Intervention Group: The training will be done face to face and numbers will be used to maintain the time-to-exhalation ratio. The training will last for 10 minutes. prone position intervention group: Patients will first be in the supine position for 30 minutes. The patient will then lie on his stomach or back for 30 minutes and the respiratory symptoms will be re-measured at 15 and 30 minutes and their average will be recorded as desired. Combined intervention group deep breathing and prone position: The intervention in the group of deep breathing and supine position will be combined.

Main outcome variables

Dyspnea, Cough, Breathing and Blood oxygen saturation level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210423051056N1**

Registration date: **2021-06-18, 1400/03/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-18, 1400/03/28**

Update count: **0**

Registration date

2021-06-18, 1400/03/28

Registrant information

Name

Sima Alipour Nasrabadsofla

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3333 7001

Email address

kianoosh.a1381wolf@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The combined effect of deep breathing and prone position on common respiratory symptoms in patients with COVID-19

Public title

The combined effect of deep breathing and prone position on common respiratory symptoms in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 85 years Ability to communicate and answer questions Consent to participate in the study and sign the informed consent form The patient is alert The patient should not be intubated The percentage of oxygen saturation of the patient's blood is below 93%

Exclusion criteria:

Patient dissatisfaction with continuing the study Adverse changes in vital signs (blood oxygen saturation level, heart rate, respiration and blood pressure)

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Block random allocation will be done in such a way that according to the number of study groups (three groups) including intervention 1 (deep breathing), intervention 2 (prone position) and intervention 3 (combination of deep breathing and prone position) And according to the calculated factorial law, ie $6 = 1 + 2 + 3 =! 3$, all possible arrangements of individuals considering A for the intervention group 1 (deep breathing), B for the intervention group 2 (prone position) And C will be developed for intervention group 3 (combination of deep breathing and prone position). Then, since the estimated sample size was 96 people, in each block, three samples, each of which represents a study group and their order of arrangement will be different, from these blocks, sampling will be done by placement.

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 Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

City

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Postal code

7591741417

Approval date

2021-05-15, 1400/02/25

Ethics committee reference number

IR.YUMS.REC.1400.024

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

u07.1

ICD-10 code description

U07.1: COVID-19, Virus identified

Primary outcomes**1****Description**

Dyspnea

Timepoint

Patients' rate of Dyspnea at the beginning of the study (before the intervention) and immediately after the start of the study

Method of measurement

Borg's Category Ratio Scale (CR10) and Visual Analog Scales (VAS)

2**Description**

Cough

Timepoint

Number of patients coughing at the beginning of the study (before the intervention) and immediately after the start of the study

Method of measurement

Record the number of coughs using a checklist prepared by the researcher

3

Description

Breathing

Timepoint

The number of patients breathing at the beginning of the study (before the intervention) and immediately after the start of the study

Method of measurement

Record the number of breathing using a checklist prepared by the researcher

4

Description

Blood oxygen saturation level

Timepoint

Percentage of blood oxygen saturation of patients at the beginning of the study (before the intervention) and immediately after the start of the study

Method of measurement

Pulse oximeter connected to the monitor model LK88

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: deep breathing: This intervention will be taught individually and orally by the researcher. In this way, the patient will be asked to perform the inhalation and exhalation operation in a ratio of 4 to 6, ie the inhalation operation through the nose and counting 1 to 4, and the exhalation operation through the mouth and counting 1 to 6. This training will be done face to face and numbers will be used to maintain the time to exhale ratio. A written guide will also be provided to patients. The training will last for 10 minutes and includes; 1. Place your tongue motionless in the palm of your mouth. 2. Breathe slowly and deeply and regularly (deep and slow inhale, exhale, rest.) And 3. Do not talk during the procedure, it will be. The skill of the samples in performing the exercises will be evaluated by the researcher and after training the patient will be asked to practice this task in order to achieve sufficient skills in this field.

Category

Treatment - Other

2

Description

Intervention group 2: prone position: The procedure for performing the intervention in the supine group will be that the patients will first be in the supine position for 30 minutes and before changing the position, the respiratory symptoms will be measured and recorded. The patient will then lie on his stomach or back for 30 minutes and the respiratory symptoms will be re-

measured at 15 and 30 minutes. For more accuracy, respiratory symptoms will be measured 3 times at 15-second intervals each time the measurement will be recorded as the desired value.

Category

Treatment - Other

3

Description

Intervention group 3: combination of deep breathing and prone position: The intervention will be performed in the group of deep breathing and supine position in combination, as in the previous two groups and in combination.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Jalil Hospital

Full name of responsible person

Sima Alipour Nasrabadsofla

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Shahid Jalil Hospital, Qarani Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Mari Oryad

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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

Yasouj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Sima Alipour Nasrabadsofla

Position

Master student of Medical-Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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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