Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

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
Street address
Shahid Jalil Hospital, Qarani Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591387493
Phone
+98 74 3333 7001
Email
simaalipour90@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Hossein Mari Oryad
Street address
Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Phone
+98 74 1333 7251

Fax
+98 74 3333 7230
Email
nursing@yums.ac.ir
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
Street address
Shahid Jalil Hospital, Qarani Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591833769
Phone
+98 74 3333 7001
Email
simaalipour90@gmail.com

Person responsible for scientific 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
Street address
Shahid Jalil Hospital, Qarani Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran
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Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591833769
Phone
+98 74 3333 7001
Email
simaalipour90@gmail.com

Person responsible for updating data

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
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Street address
Shahid Jalil Hospital, Qarani Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran
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Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591833769
Phone
+98 74 3333 7001
Email
simaalipour90@gmail.com

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