

# 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**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**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-Boyerahmad

##### **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**

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##### **Province**

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##### **Phone**

+98 74 1333 7251

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+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

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+98 74 3333 7001

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**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**

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

Yasouj University of Medical Sciences

**Full name of responsible person**

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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