

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigation of the effects of prone position on respiratory status, hemodynamics, hospital stay and transfer to intensive care unit in patients with Covid-19: A randomized controlled clinical trial

#### Protocol summary

##### Study aim

Investigation of the effects of prone position on respiratory status, hemodynamic, hospital stay and transfer to intensive care unit in patients with Covid-19

##### Design

The clinical trial is a randomized controlled trial with parallel groups in 74 patients

##### Settings and conduct

Intervention group: For the first time, the participant is placed in a prone position for 90 minutes. After evaluating the initial outcome, participants are asked to be in the prone position between 20 or 30 minutes of tolerance every three hours during hospitalization, so that the total time in the prone position is between 6 or 8 in 24 hours, and then the secondary outcome will be evaluated. Control group: For the first time, participants are asked to be in the supine position for 90 minutes. After evaluating the primary outcomes, the patient is asked to rest in his or her normal position, and then the secondary outcomes are evaluated.

##### Participants/Inclusion and exclusion criteria

All patients with COVID-19 based on the standard diagnostic test and the presence of at least one respiratory symptom include the study and in the following cases will exclude from the study: Patient intolerance Severe hemodynamic and respiratory changes greater than 20% of baseline Severe cough Nausea and vomiting during the position

##### Intervention groups

Intervention group or prone position group Control group or common position group

##### Main outcome variables

Hemodynamic status and respiratory status include o<sub>2</sub> saturation, respiration rate, shortness of breath, mean arterial blood pressure, and pulse rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160126026217N4**

Registration date: **2020-06-08, 1399/03/19**

Registration timing: **prospective**

Last update: **2020-06-08, 1399/03/19**

Update count: **0**

##### Registration date

2020-06-08, 1399/03/19

##### Registrant information

##### Name

Sajad Yarahmadi

##### Name of organization / entity

Iran University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3322 5655

##### Email address

yarahmadi.s@tak.iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-09-20, 1399/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigation of the effects of prone position on respiratory status, hemodynamics, hospital stay and transfer to intensive care unit in patients with Covid-19: A randomized controlled clinical trial

### Public title

Investigation of the effects of prone position on cardiac and respiratory status in patients with Coronavirus

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

All patients with COVID-19 based on standard diagnosed test and had at least one respiratory symptom Age between 18 and 65 years Willing to participate in the study

#### Exclusion criteria:

Do not use mechanical ventilation devices Absence of respiratory diseases such as asthma and COPD Not suffering from hypertension No history of heart failure No history of orthopedic and spinal problems No history of neurological diseases Lack of anemia Lack of treatment-induced pulmonary complications such as barometer and chest tube installation No history of thoracic surgery in the last 6 months

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **74**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The patients by block randomization assigned in intervention and control groups. Classification is done using a random number table. Classes by age(below 50 years/ older 50 years) and gender (male/female). It should be noted that the volume of each block is 4 cases, thus creating 6 different combinations of 4 blocks and randomly selecting the blocks. Blocking and allocation sequences for concealment will be done by the non-involved researcher.

### 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 Lorestan University of Medical Sciences

##### Street address

Lorestan University of Medical Sciences, Anooshirvan Rezaei Square

##### City

Khorramabad

##### Province

Lorestan

##### Postal code

6813833946

##### Approval date

2020-05-06, 1399/02/17

##### Ethics committee reference number

IR.LUMS.REC.1399.059

## Health conditions studied

### 1

#### Description of health condition studied

Covid-19

#### ICD-10 code

RA01.0

#### ICD-10 code description

Covid-19

## Primary outcomes

### 1

#### Description

Mean blood pressure

#### Timepoint

At 0, 30, 60, 90 and 120 minutes after the first intervention

#### Method of measurement

Digital sphygmomanometer

### 2

#### Description

Heart rate

#### Timepoint

At 0, 30, 60, 90 and 120 minutes after the first intervention

#### Method of measurement

Pulse oximeter device

### 3

#### Description

Oxygen saturation

#### Timepoint

At 0, 30, 60, 90 and 120 minutes after the first intervention

**Method of measurement**

Pulse oximeter device

**4****Description**

Respiratory rate

**Timepoint**

At 0, 30, 60, 90 and 120 minutes after the first intervention

**Method of measurement**

Count the number of breaths per minute

**5****Description**

Breath shortness

**Timepoint**

At 0, 30, 60, 90 and 120 minutes after the first intervention

**Method of measurement**

Visual analog scale for breath shortness

**Secondary outcomes****1****Description**

Hospital stay

**Timepoint**

Patient discharge time

**Method of measurement**

Count the number of days a patient is hospitalized

**2****Description**

Percentage of patients transferred to the intensive care unit

**Timepoint**

At the end of the study

**Method of measurement**

Percentage of the number of patients who will be transferred to the intensive care unit

**3****Description**

Mortality rate of patients

**Timepoint**

At the end of the study

**Method of measurement**

The number of patients who die by the end of the study

**Intervention groups****1****Description**

Intervention group: In this group, participants will be in the prone position for 90 minutes for the first time. After evaluating the initial outcomes, the participant will be

asked to be in the prone position for 6 to 8 hours until the clearance time, and then the secondary outcomes will be evaluated.

**Category**

Treatment - Other

**2****Description**

Control group: In this group, participants will be in their usual position for 90 minutes for the first time, after evaluating the initial outcomes, the participant will be asked to be in his usual positions until the time of discharge, and then the secondary outcomes will be evaluated.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shohadaye Ashayer hospital

**Full name of responsible person**

Sajad Yarahmadi

**Street address**

Shohadaye Ashayer hospital, Enghlab Blvd

**City**

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**Postal code**

6813833946

**Phone**

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**Fax**

+98 66 3322 0105

**Email**

s.yarahmadi000@gmail.com

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Ebrahim Falahi

**Street address**

Lorestan university medical sciences, km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village

**City**

Khorramabad

**Province**

Lorestan

**Postal code**

381251698

**Phone**

+98 66 3312 0172

**Fax**

+98 66 3312 0173

**Email**

research@lums.ac.ir

**Web page address**

http://research.lums.ac.ir/index.php?module=web\_directory&wd\_id=4664

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Khoram-Abad 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

**Name of organization / entity**

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Sajad Yarahmadi

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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s.yarahmadi000@gmail.com

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

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

Sajad Yarahmadi

**Position**

Faculty member

**Latest degree**

Master

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

Khoram-Abad University of Medical Sciences

**Full name of responsible person**

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**Position**

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Master

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**Email**

s.yarahmadi000@gmail.com

**Person responsible for scientific inquiries****Contact****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