

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 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 o2 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

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3323 6401

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

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

Other areas of specialty/work
Nursery

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

City
Khorramabad

Province
Lorestan

Postal code
381251698

Phone
+98 66 3324 3143

Fax
+98 66 3312 0173

Email
s.yarahmadi000@gmail.com

Person responsible for scientific 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

Other areas of specialty/work
Nursery

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

City
Khorramabad

Province
Lorestan

Postal code
381251698

Phone
+98 66 3324 3143

Fax
+98 66 3312 0173

Email
s.yarahmadi000@gmail.com

Person responsible for updating data

Contact

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

City
Khorramabad

Province
Lorestan

Postal code
381251698

Phone
+98 66 3324 3143

Fax
+98 66 3312 0173

Email
s.yarahmadi000@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