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)

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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
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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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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