Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of prone and orthopnea positions versus supine position on comfort, dyspnea and arterial blood oxygen saturation in patients with Covid-19: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of prone and orthopnea positions versus supine position on comfort, dyspnea and arterial blood oxygen saturation in patients with Covid-19

Design
This is a randomized clinical trial with control group, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the Golastan Hospital in Kermanshah city on 90 eligible patients. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 60 years; Covid-19 infection; Conscious; Mild to moderate arterial oxygen saturation (80% to 90%); Exclusion criteria: Pregnancy; Obesity; Abdominal ulcers

Intervention groups
Intervention group 1: Laying the patient in the prone position for 30 minutes Intervention group 2: Laying the patient in the orthopedic position for 30 minutes Control group: Laying the patient in the supine position for 30 minutes

Main outcome variables
Primary outcome: Arterial blood oxygen, feeling comfortable, the severity of dyspnea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N425**
Registration date: **2022-05-10, 1401/02/20**
Registration timing: **prospective**

Last update: **2022-05-15, 1401/02/25**
Update count: **1**

Registration date
2022-05-10, 1401/02/20

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of prone and orthopnea positions versus supine position on comfort, dyspnea and arterial blood oxygen saturation in patients with Covid-19: a randomized

clinical trial

Public title
Effect of prone and orthopnea positions versus supine position on comfort, dyspnea and arterial blood oxygen saturation in patients with Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 60 years; Covid-19 infection; Conscious; Mild to moderate arterial oxygen saturation (80% to 90%);
Exclusion criteria:
Pregnancy; Obesity; Abdominal ulcers
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2022-05-07, 1401/02/17
Ethics committee reference number
IR.UMSHA.REC.1401.134

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
U07.1
ICD-10 code description
Covid-19

Primary outcomes

1

Description
Arterial blood oxygen
Timepoint
Before the intervention and 10 and 30 minutes after the intervention
Method of measurement
By using Mark Beurer pulse oximeter model P030 made in Germany

2

Description
Feeling comfortable
Timepoint
Before the intervention and 10 and 30 minutes after the intervention
Method of measurement
Using the visual analog scale (VAS)

3

Description
The severity of dyspnea
Timepoint
Before the intervention and 10 and 30 minutes after the intervention
Method of measurement
Using the analog visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Laying the patient in the prone position for 30 minutes
Category
Treatment - Other

2

Description
Intervention group 2: Laying the patient in the orthopedic position for 30 minutes
Category
Treatment - Other

3

Description
Control group: Laying the patient in the supine position for 30 minutes
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Golastan Hospital in Kermanshah city
Full name of responsible person
Maryam Rezaei
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
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Position
Student of Nursery
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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