

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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

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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

Street address

Golastan Hospital, Boostan Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Full name of responsible person

Maryam Rezaei

Position

Student of Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Person responsible for scientific inquiries

Contact

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Hamedan University of Medical Sciences

Full name of responsible person

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Position

Disaster and Emergency Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Health in Emergency and Disaster

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

Hamedan University of Medical Sciences

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Position

Professor of Epidemiology

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Ph.D.

Other areas of specialty/work

Epidemiology

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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