

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the effect of three tripod, Semi-sitting and prone positions on vital signs and comfort pattern of patients with covid-19

Protocol summary

Study aim

Determining the effect of semi-sitting position (group A (, tripod (group B)) and lower back (group C) on vital signs and comfort pattern in patients with COVID19

Design

In this clinical trial, 90 eligible patients will be selected and placed in three groups A, B, C. This study will be performed on three groups, one control group and two intervention groups. The study is double-blind with parallel groups, randomized. In this study, phase is not applicable. Rand function in Excel software will also be used for randomization.

Settings and conduct

This study will be performed in Amir Al-Momenin Hospital in Arak. Participants' expert and sample collector do not know how to randomize.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infection by coronavirus (positive PCR test), age 20 to 70 years, willingness to participate in research, lack of connection to a mechanical ventilator (no intubation), ability to communicate, no underlying respiratory disease, no pregnancy, No history of abdominal surgery during the last 6 months (for placement in the lumbar position), having lung involvement of at least 10% with shortness of breath
Exclusion criteria: patient death, unwillingness to participate in further research, patient intubation during research, abdominal obesity, abdominal surgery recently

Intervention groups

Patients admitted to corona wards to measure the effect of three semi-sitting , tripod and prone positions on vital signs and patients' comfort pattern.

Main outcome variables

Improve vital signs and comfort pattern

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171203037733N3**

Registration date: **2021-05-11, 1400/02/21**

Registration timing: **prospective**

Last update: **2021-05-11, 1400/02/21**

Update count: **0**

Registration date

2021-05-11, 1400/02/21

Registrant information

Name

Mehran Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3417 3505

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m.akbari@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of three tripod, Semi-sitting and prone positions on vital signs and comfort pattern of patients with covid-19

Public title

The effect of body position on vital signs and comfort pattern of patients with coronary disease

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Infection with Corona virus (positive PCR test) Age 20 to 70 years Willingness to participate in research No connection to mechanical ventilation (no intubation) Ability to communicate No underlying respiratory disease No pregnancy No history of abdominal surgery during the last 6 months (for placement in the lumbar position) Have at least 10% lung involvement with shortness of breath

Exclusion criteria:

Patient death Reluctance to participate in further research Intubation of the patient during the research Abdominal obesity Abdominal surgery recently

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

First, patients are selected easily and entered into the study. They will then be randomly assigned (Simple randomized block assignment) to three groups A, B and C By statistical software. Control group A in a semi-sitting position Intervention group B in tripod position Intervention group C in the prone position Rand function in Excel software will also be used for randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

This research is a clinical trial with three groups (two intervention groups and one control group) that the method of blinding in this study is double-blind that the main researcher and statistical analyzer have been blinded. In this way, the relevant checklists are coded according to codes B, A and C, and the sampler puts people in different positions according to randomly selected codes, and after collecting information by the sampler, this The information is entered by the data analyzer in SPSS statistical software and after extracting the obtained results, accurate analysis can be reported.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Khomein University of Medical Sciences

Street address

Azadi St., Khomein University of Medical Sciences

City

Khomein

Province

Markazi

Postal code

38817-43364

Approval date

2021-05-01, 1400/02/11

Ethics committee reference number

IR.KHOMEIN.REC.1400.001

Health conditions studied**1****Description of health condition studied**

coronavirus

ICD-10 code

RA01.0

ICD-10 code description

Covid-19

Primary outcomes**1****Description**

Vital signs

Timepoint

Before and after the intervention

Method of measurement

Heart rate, blood pressure and respiration rate

2**Description**

Comfort

Timepoint

Before and after the intervention

Method of measurement

Based on the Kolcaba questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: This group of patients is in group B, which is in the tripod position. Questionnaires related to demographic information, vital signs and patients' comfort level are completed before the intervention.

Group B patients are placed in a tripod position and within 15 and 60 minutes, the patient's vital signs and comfort pattern are re-evaluated and recorded in the relevant questionnaire.

Category

Other

2

Description

Intervention group2: This group of patients is in group C, which is in the prone position. Questionnaires related to demographic information, vital signs and patients' comfort level are completed before the intervention.

Group C patients are placed in the prone position and within 15 and 60 minutes, the patient's vital signs and comfort pattern are re-evaluated and recorded in the relevant questionnaire.

Category

Other

3

Description

Control group: Patients in group A are classified as patients in the control group who complete questionnaires related to demographic information, vital signs and patient comfort before the intervention. Group A patients are placed in a semi-sitting position with an angle of 30 degrees and within 15 and 60 minutes, the patient's vital signs and comfort pattern are re-evaluated and recorded in the relevant questionnaire.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital in Arak

Full name of responsible person

Mehran Akbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khomein University of Medical Sciences

Full name of responsible person

Mojtaba Didehdar

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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

Khomein 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

Khomein university of Medical Sciences

Full name of responsible person

Mehran Akbari

Position

instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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