

# 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)

##### Phone

+98 86 3417 3505

##### Email address

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

##### Street address

Azadi St., Khomein School of Medical Sciences, Khomein, Iran

##### City

Khomein

##### Province

Markazi

##### Postal code

38817-43364

#### Phone

+98 86 4622 1534

#### Email

mehranakbari1373@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Khomein University of Medical Sciences

##### Full name of responsible person

Mojtaba Didehdar

##### Street address

Azadi St., Khomein School of Medical Sciences, Khomein, Iran

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

mehranakbari1373@yahoo.com

#### 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

##### Street address

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## Person responsible for scientific 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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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Latest degree**

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+98 86 4622 1534

**Email**

mehranakbari1373@yahoo.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