

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of postural drainage on physiological parameters of patients with covid-19 hospitalized in critical care unit

#### Protocol summary

##### Study aim

Effect of postural drainage on physiological parameters of patients with covid-19 hospitalized in critical care unit

##### Design

The study will be double blind and clinical trial. 90 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3

##### Settings and conduct

Patients with medium to critical grade Covid-19 without intubation with respiratory symptoms in khansari and amiralmomenin Hospital in Arak are divided into 2 groups by simple randomization with blocks. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Medium to critical grade Covid-19 without intubation with respiratory symptoms; need to receive oxygen more than 4 to 6 liters per minute with a simple mask with storage bag without re-breathing; apache score less than 25; no acute asthma, and other lung diseases such as pulmonary edema, heart and lung disease  
Exclusion criteria: death; transfer to the ward; intubation; unwillingness to participate in the study

##### Intervention groups

Intervention group: In this group, patients, in addition to routine ward care, will be placed in special posture evacuation situations and will be used to move pulmonary secretions and direct them to the central airways due to the force of gravity. Positions are performed in three shifts in the morning, evening and night for ten minutes. Control group: In this group, patients will receive routine care in the intensive care unit, including chest physiotherapy.

##### Main outcome variables

Breathing rate; oxygen saturation percentage; blood carbon dioxide pressure; blood pH; blood bicarbonate; need to get oxygen; number of coughs

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220618055209N1**

Registration date: **2022-06-23, 1401/04/02**

Registration timing: **prospective**

Last update: **2022-06-23, 1401/04/02**

Update count: **0**

##### Registration date

2022-06-23, 1401/04/02

##### Registrant information

##### Name

Pegah Nazari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3224 4693

##### Email address

nazari.pegah98@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-06, 1401/04/15

##### Expected recruitment end date

2023-07-06, 1402/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of postural drainage on physiological parameters of patients with covid-19 hospitalized in critical care unit

#### Public title

Effect of postural drainage on physiological parameters of patients with covid-19 hospitalized in critical care unit

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Medium to critical grade Covid-19 without intubation with respiratory symptoms Positive PCR test Need to receive more than 4 to 6 liters of oxygen per minute with a simple mask with non-rebreathing storage bag Apache score less than 25 18 to 75 years Absence of acute asthma, and other lung diseases such as pulmonary edema, heart and lung disease

##### Exclusion criteria:

Reluctance to participate in the study Do not perform any of the evacuation situations Intubation during study Transfer the patient to the ward Death

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **90**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The study is double-blind. The analysis is done by the analyst and outcome evaluator (two-blind) and the participant. Analysts, evaluators and participants are not aware of the consequences of grouping.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2021-11-28, 1400/09/07

#### Ethics committee reference number

IR.ARAKMU.REC.1400.246

## Health conditions studied

### 1

#### Description of health condition studied

Patients with Covid-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Breathing rate

#### Timepoint

Before and immediately after each intervention

#### Method of measurement

Physical examination

### 2

#### Description

Oxygen saturation percentage

#### Timepoint

Before and immediately after each intervention

#### Method of measurement

Pulse oximetry

### 3

#### Description

Blood carbon dioxide pressure

#### Timepoint

At the beginning and end of the study

#### Method of measurement

Venous blood gas sample test

## 4

### **Description**

Blood pH

### **Timepoint**

At the beginning and end of the study

### **Method of measurement**

Venous blood gas sample test

## 5

### **Description**

Blood bicarbonate

### **Timepoint**

At the beginning and end of the study

### **Method of measurement**

Venous blood gas sample test

## 6

### **Description**

Need to get oxygen

### **Timepoint**

Immediately after the intervention, one hour after each intervention and the day after the last intervention

### **Method of measurement**

Physical examination

## 7

### **Description**

Number of coughs

### **Timepoint**

Up to one hour after the end of each intervention and the next day at the end of the intervention time

### **Method of measurement**

Physical examination

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In this group, patients, in addition to routine ward care, will be placed in special posture evacuation situations and will be used to move pulmonary secretions and direct them to the central airways due to the force of gravity. Positions are performed in three shifts in the morning, evening and night for ten minutes. In each shift, three positions will be performed for the patients. The evening shift will take the position of the arch with a 45-degree angle in the upper body and a 20-degree angle in the waist. The night shift will receive the prone position and the right lateral and left lateral positions at a 45 degree angle to the bed. In each shift, the total positioning time will take a total of 30 minutes.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: In this group, patients will receive routine care in the intensive care unit, including chest physiotherapy.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Amiralmomenin hospital

##### **Full name of responsible person**

Dr seyed Yousef Shahtaheri

##### **Street address**

Amiralmomenin hospital, Sardasht

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

3814957558

##### **Phone**

+98 86 3417 3630

##### **Email**

yousef.sh00@gmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Khansari hospital

##### **Full name of responsible person**

Dr seyed Yousef Shahtaheri

##### **Street address**

Khansari hospital, Daneshgah street

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

3818649433

##### **Phone**

+98 86 3367 5007

##### **Email**

yousef.sh00@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Dr Alireza Kamali

##### **Street address**

Research Center, Payambar Azam Complex, Basij

square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3848176941

**Phone**

+98 86 3417 3645

**Email**

alikamaliir@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Seyed Yousef Shahtaheri

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Valiasr Hospital, Valiasr square, Shahid Shirodi street

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Email**

yousef.sh00@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Davood Hekmatpou

**Position**

Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Nursery

**Street address**

Payambar Azam complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3417 3505

**Email**

hekmatpou@yahoo.com

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

Arak University of Medical Sciences

**Full name of responsible person**

Pegah Nazari

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Payambar Azam complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3224 4693

**Fax****Email**

Nazari.pegah98@gmail.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