

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

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2

Recruitment center

Name of recruitment center

Khansari hospital

Full name of responsible person

Dr seyed Yousef Shahtaheri

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Khansari hospital, Daneshgah street

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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

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Davood Hekmatpou

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

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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

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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