

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The effect of priority of chest physiotherapy and prone position on respiratory indicators in patients with covid 19: Randomize clinical trial

#### Protocol summary

##### Study aim

Introducing a more effective treatment protocol to increase blood oxygen level, prevent disease progression, improve respiratory tidal volume and lung function in Covid 19 patients.

##### Design

Two groups, crossover, double blind, with random sequence by block randomization method on 30 patients. Random allocation software is used for randomization.

##### Settings and conduct

This clinical trial will be performed in Imam Khomeini Hospital. Patients are divided into two groups include the priority group of chest physiotherapy over the prone position and the priority group of prone position over the chest physiotherapy by using random sequencing method. Respiratory indicators will be recorded before the the first session and at the end of the last session for statistical analysis. The study is double blind and participants and evaluator and data analyst are blind to the type of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 35 to 75 years old patients, affected by Covid 19, consciousness, in the progressive or acute phase of corona disease and similar in type and dose of medication received. Exclusion criteria: patients under mechanical ventilation, with neurological disorders, undergoing surgery in the chest or abdomen area in the last 4 months, with blood coagulation disorders, with history of thrombosis or pulmonary embolism, with active bleeding in the chest area or rib fracture.

##### Intervention groups

Group 1: In 6 sessions, first chest physiotherapy (CPT) for 30 minutes and then for 3 hours prone position will be done. group 2: In 6 sessions, first prone position for 3 hours and then CPT will be performed for 30 minutes.

##### Main outcome variables

oxygen saturation percentage(Spo2): partial pressure of oxygen(Pao2): fraction of inspired oxygen(Fio2): Pao2/Fio2: forced vital capacity(FVC): forced expiratory

volume in first second(FEV1): FEV1/FVC

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210505051181N2**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

##### Registration date

2022-01-29, 1400/11/09

##### Registrant information

##### Name

Mehrnaz Kajbafvala

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2304 6688

##### Email address

kajbafvala.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of priority of chest physiotherapy and prone position on respiratory indicators in patients with covid 19: Randomize clinical trial

### Public title

Evaluation of the effect of priority of chest physiotherapy and prone position in covid 19

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

People who have been hospitalized for Covid 19 and are fully conscious Covid 19 affection have been confirmed by laboratory findings (CT scan, PCR test and serology test) and infectious disease specialist and the patient does not need mechanical ventilation Based on the classification of Covid 19 phases in radiological findings, patient should be in the progressive or acute phase Patients should be the same in terms of medication type and dose (Corticosteroids and Remdesivir)

#### Exclusion criteria:

Patients who need mechanical ventilation due to the severe progression of the disease Patients with neurological disorders Patients with history of chest or abdominal surgery in the last 4 months Patients with blood coagulation disorders Patients with active bleeding in the chest area or rib fractures

### Age

From **35 years** old to **75 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Outcome assessor

### Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each participant, depending on the type of intervention group, receives chest physiotherapy first and then prone position, or these interventions in the reverse order.

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this study, the limited randomization method of block randomization will be used. Blockage is usually used to balance the number of samples allocated to each of the studied groups. The size of all the blocks is equal and in this trial which includes 30 patients in 2 groups, we will have blocks with size of 6. Random allocation software is also used for randomization. In order to conceal allocation of participants to the groups, sequentially numbered, sealed, opaque envelopes (SNOSE) will be used

### Blinding (investigator's opinion)

Double blinded

### Blinding description

This study is a double blind study. Examiners of this study, who assess patients respiratory indicators, will be unaware of the randomization process and assignment of participants to each group and this will be done by someone else and thus bias is prevented. Patients also unaware of how to group. It should be noted that the therapist is aware of how to group and the patient in each group.

### Placebo

Not used

### Assignment

Crossover

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2021-10-16, 1400/07/24

#### Ethics committee reference number

IR.IUMS.REC.1400.646

## Health conditions studied

### 1

#### Description of health condition studied

COVID19, virus identified

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID19, virus identified

### 2

#### Description of health condition studied

COVID 19 virus not identified

#### ICD-10 code

U07. 2

#### ICD-10 code description

COVID 19 virus not identified

## Primary outcomes

### 1

#### Description

oxygen saturation percentage

#### Timepoint

before beginning physiotherapy interventions and after completion 6 physiotherapy sections corresponding to each group

#### Method of measurement

pulse oximetry

### 2

#### Description

partial pressure of oxygen ( Pao<sub>2</sub>)

#### Timepoint

before beginning physiotherapy interventions and after completion 6 physiotherapy sections corresponding to each group

#### Method of measurement

arterial blood gases (ABG)

### 3

#### Description

forced vital capacity (FVC)

#### Timepoint

before beginning physiotherapy interventions and after completion 6 physiotherapy sections corresponding to each group

#### Method of measurement

spirometer

### 4

#### Description

forced expiratory volume in the first second (FEV<sub>1</sub> )

#### Timepoint

before beginning physiotherapy interventions and after completion 6 physiotherapy sections corresponding to each group

#### Method of measurement

spirometer

## Secondary outcomes

### 1

#### Description

fraction of inspired oxygen (Fio<sub>2</sub>)

#### Timepoint

before beginning physiotherapy interventions and after completion 6 physiotherapy sections corresponding to each group

#### Method of measurement

oxygen meter

### 2

#### Description

partial pressure of oxygen to fraction of inspired oxygen

ratio (Pao<sub>2</sub>/Fio<sub>2</sub>)

#### Timepoint

before beginning physiotherapy interventions and after completion 6 physiotherapy sections corresponding to each group

#### Method of measurement

mathematical calculation

### 3

#### Description

forced expiratory volume in the first second to forced vital capacity ratio (FEV<sub>1</sub>/FVC)

#### Timepoint

before beginning physiotherapy interventions and after completion 6 physiotherapy sections corresponding to each group

#### Method of measurement

mathematical calculation

## Intervention groups

### 1

#### Description

Intervention group 1: In this group in 6 sessions, chest physiotherapy will be performed once a day for 30 minutes. Chest physiotherapy procedures performed in this group are: 1- Percussion in which the physiotherapist with free wrist and hand in a cup and hollow position transmits energy to the peripheral airways by performing rhythmic clapping on the chest. 2- Vibration, in which a series of small oscillating movements are performed by the hands on the chest wall, while exhaling after performing a deep breath. 3- Diaphragmatic breathing in which the patient is required to have abdominal breathing. 4- Segmental breathing: In this method, the patient sits comfortably, the physiotherapist places his hand on both sides of the chest in different lobes of the patient's lungs and asks the person to guide the air under the therapist's hand while breathing so that the therapist's hand movement can be seen and other parts of the lungs are relaxed. After performing chest physiotherapy techniques, patients will be in a prone position for 3 hours on the same day.

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: In 6 sessions, patients are first placed in a prone position for 3 hours a day. Then on the same day, chest physiotherapy will be performed for 30 minutes. Same as intervention group1, chest physiotherapy procedures performed in this group are: 1- Percussion in which the physiotherapist with free wrist and hand in a cup and hollow position transmits energy to the peripheral airways by performing rhythmic clapping on the chest. 2- Vibration, in which a series of small oscillating movements are performed by the hands on the chest wall, while exhaling after performing a deep

breath. 3- Diaphragmatic breathing in which the patient is required to have abdominal breathing. 4- Segmental breathing: In this method, the patient sits comfortably, the physiotherapist places his hand on both sides of the chest in different lobes of the patient's lungs and asks the person to guide the air under the therapist's hand while breathing so that the therapist's hand movement can be seen and other parts of the lungs are relaxed.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital Complex

##### Full name of responsible person

Ali Rezaee Chamanabad

##### Street address

Keshavarz Blvd. Gharib St. Imam Khomeini Hospital Complex

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۱۹۷۳۳۱۴۱

##### Phone

+98 21 6119 0000

##### Email

Imamhospital@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Seyyed Abbas Motevalian

##### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 8670 2503

##### Email

research-m@iums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Ali Rezaee Chamanabad

##### Position

student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Physiotherapy

##### Street address

Unit 8, Arman Building, 3rd East Alley, Bustan Alley, Golestan St., Central Janatabad St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1475654343

##### Phone

+98 21 4604 8909

##### Email

alireza722012@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Mehrnaz Kajbafvala

##### Position

Assistant professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Physiotherapy

##### Street address

Shahid Shahid Dastgerdi (Zafar) Ave, Aliasghar Children Hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1919816766

**Phone**

+98 21 2304 6688

**Fax**

**Email**

kajbafvala.m@iums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Ali Rezaee Chamanabad

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

Unit 8, Arman Building, 3rd East Alley, Bustan Alley,  
Golestan St., Central Janatabad St

**City**

Tehran

**Province**

Tehran

**Postal code**

1475654343

**Phone**

+98 21 4604 8909

**Email**

alireza722012@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Data can be shared after making participants  
unrecognizable.

### When the data will become available and for how long

Start access period 6 months after the results publication

### To whom data/document is available

People in medicine and rehabilitation field

### Under which criteria data/document could be used

Performing any analysis to any data resulted from this  
study will be allowed only with the permission of  
corresponding author.

### From where data/document is obtainable

Email the researcher- Ali Rezaee-  
alireza722012@yahoo.com

### What processes are involved for a request to access data/document

6 months after the publication of the results, information  
will be given to the applicant within a week by emailing  
the researcher.

### Comments