

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of chest physiotherapy on the clinical outcomes of patients with COVID 19

#### Protocol summary

##### Study aim

The effect of chest physiotherapy on the clinical outcomes of patients with COVID 19

##### Design

Clinical trial with control group, with parallel groups, randomized, phase 2 with the help of Med-calc statistical software, with 95% power and 1% error, 52 cases were determined.

##### Settings and conduct

The current study is a randomized clinical trial that will be conducted on 52 patients with covid-19 admitted to Shahada Izeh Hospital. Due to the necessity of having the entry criteria and also the limited samples, random sampling will be based on the purpose. First, the clinical status of the two groups of patients will be measured by the clinical status survey form, and then the chest physiotherapy program will be tested in the test group. no need for blinding in this trial.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, moderate severity of the disease, being hospitalized, not suffering from any underlying diseases. The patient's alertness, able to perform chest physiotherapy activities. Exclusion criteria: suffering from respiratory failure and turning the moderate intensity of the disease into its severe type.

##### Intervention groups

After registering demographic information, patients in the intervention group will undergo chest physiotherapy in addition to routine care. Chest physiotherapy intervention will be done for six days and every morning and evening for 20 minutes. During this period, patients in the control group will receive only routine care related to the care of patients with Covid-19. At the end of the third and sixth days, the patients of both groups will be evaluated.

##### Main outcome variables

forced expiratory volume in the first second (FEV1);  
Forced vital capacity (FVC) and arterial blood test

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220815055703N1**

Registration date: **2022-11-15, 1401/08/24**

Registration timing: **retrospective**

Last update: **2022-11-15, 1401/08/24**

Update count: **0**

##### Registration date

2022-11-15, 1401/08/24

##### Registrant information

##### Name

Reza Moradi ajgil

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4363 1059

##### Email address

rezanurs73@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-07, 1401/07/15

##### Expected recruitment end date

2022-10-17, 1401/07/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of chest physiotherapy on the clinical outcomes of patients with COVID 19

#### Public title

Investigating the effect of chest physiotherapy in the treatment of covid-19

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Desire to participate in the study  
The average severity of the disease based on the diagnosis of a doctor specializing in respiratory diseases  
Hospitalization at the time of diagnosis  
Not using other chest physiotherapy programs at the same time  
Absence of underlying diseases such as cancer, cardiovascular diseases and diabetes  
Patient alertness  
Able to perform chest physiotherapy activities

##### Exclusion criteria:

Reluctance or refusal to participate in the study  
Changing the level of severity of the disease from moderate to severe level of the disease  
Having respiratory failure

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 52

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

For randomization, we use the method of block randomization with blocks with size of 4 and for this purpose, we prepare four sheets of paper. On the two sheets we write the letter I meaning "Intervention" and on the other two sheets we write the letter C meaning "Control". Mix the sheets together and place them in the desk drawer. Upon referral to any of the eligible patients, one of the sheets will be randomly pulled out and based on this sheet being drawn I or C will be assigned to one of the two intervention or comparison groups.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

##### Street address

Boulevard of Medical Sciences, Ahvaz, Khuzestan Province

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

15794 - 61357

##### Approval date

2022-07-30, 1401/05/08

##### Ethics committee reference number

IR.AJUMS.REC.1401.178

### Health conditions studied

#### 1

#### Description of health condition studied

Investigating the effect of chest physiotherapy on the recovery of patients with covid-19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

### Primary outcomes

#### 1

#### Description

Vital capacity (FEV2/FVC ratio)

#### Timepoint

Before starting the intervention and at the end of the sixth day after the start of the intervention (physiotherapy)

#### Method of measurement

Spirometry device

#### 2

#### Description

Arterial blood gases include: (PaO<sub>2</sub>), (PaCO<sub>2</sub>), (SaO<sub>2</sub>), (PaO<sub>2</sub>/FiO<sub>2</sub>)

#### Timepoint

Before starting the intervention and at the end of the sixth day after the start of the intervention (physiotherapy)

#### Method of measurement

Arterial blood test

### Secondary outcomes

#### 1

#### Description

Vital capacity Vital capacity (FEV2/FVC ratio)

#### **Timepoint**

At the end of the third and sixth days after the intervention (physiotherapy)

#### **Method of measurement**

Spirometry device

### **2**

#### **Description**

Arterial blood gases include: (PaO<sub>2</sub>), (PaCO<sub>2</sub>), (SaO<sub>2</sub>), (PaO<sub>2</sub>/FiO<sub>2</sub>)

#### **Timepoint**

At the end of the sixth day after the start of the intervention (physiotherapy)

#### **Method of measurement**

Arterial blood test

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Patients in the intervention group will undergo chest physiotherapy in addition to routine care related to the care of patients with covid-19. Chest physiotherapy intervention will be done for six days and every morning and evening for 20 minutes.

Physiotherapy of the chest will also be performed by the physiotherapist of the centers every morning and evening. At the end of the third and sixth days, the patients of both groups will be evaluated in terms of FEV1/FVC, FEV1, and FVC parameters using the clinical status survey form.

#### **Category**

Treatment - Devices

### **2**

#### **Description**

Control group: patients in the control group only receive routine care (depending on the severity of the disease and the underlying diseases of the patient, including oxygen therapy, required supportive treatments, preventive anticoagulation treatment, diagnostic tests, imaging procedures, emphasis on healthy eating and rest sufficient) related to the care of patients with covid-19 will receive. At the end of the third and sixth days, the patients of both groups will be evaluated in terms of FEV1/FVC, FEV1, and FVC parameters using the clinical status survey form.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Shohada Izeh Specialized Hospital

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

Reza Moradi Azgil

#### **Street address**

Shahada Hospital, Har Street, Izeh City, Khuzestan

#### **City**

Izeh

#### **Province**

Khuzestan

#### **Postal code**

6391967997

#### **Phone**

+98 61 4363 2823

#### **Email**

info@myreshte.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Ahvaz University of Medical Sciences

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

Dr. Mehrnoosh Zakirkish

##### **Street address**

ground floor, Ahvaz, Jundishapur University of Medical Sciences and Healthcare Services, Vice-Chancellor for Research and Technology, Ahvaz Academic City.

##### **City**

Ahvaz

##### **Province**

Khuzestan

##### **Postal code**

15794 - 61357

##### **Phone**

+98 61 3336 2414

##### **Email**

itc@ajums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

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

Reza Moradi Azgil

**Position**

Master's student in nursing majoring in internal surgery

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

No. 17 Amar St

**City**

lezh

**Province**

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rezanurs73@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Reza Moradi Azgil

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## Person responsible for updating data

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Reza Moradi Azgil

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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