Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Khouzestan
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: (PaO2), (PaCO2), (SaO2), (PaO2/FiO2)
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: (PaO2), (PaCO2), (SaO2), (PaO2/FiO2)

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

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6391967997

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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.

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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

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Person responsible for scientific inquiries

Contact

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Position
Master's student in nursing majoring in internal surgery

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Person responsible for updating data

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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