Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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 unware 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

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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 (Pao2)
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 (FEV1)
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 (Fio2)
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 (Pao2/Fio2)
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 (FEV1/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

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Sponsors / Funding sources

1

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Name of organization / entity
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Full name of responsible person
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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

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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 form 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