

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of pulmonary rehabilitation and prone position on respiratory parameters in patients with COVID-19 admitted to non- specialized ward of Hajar hospital of Shahrekord; a double blind randomized clinical trial

Protocol summary

Study aim

Determining the rate of changes in respiratory parameters and disease course in patients with moderate to severe Covid-19 infection by changing body position from supine to prone and pulmonary rehabilitation.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized on 105 patients. Randomized with random allocation software

Settings and conduct

In the two intervention groups, in addition to standard treatment measures, patients will be in a supine position for a maximum of two hours daily for one week and will undergo pulmonary rehabilitation for 15 minutes by a trained nursing expert. It will be recorded minutes after being in the prone position and also 60 minutes after the patient is in the supine position.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Covid-19 positive patients admitted to non-specialized wards, from 18 to 75 years old, non-intubated, under treatment, oxygen support, no bed sores on shoulder, knee and face, estimated weight less than 100 kg. Exclusion criteria: Patients with increased cerebral pressure, patients with increased intraocular pressure, dissatisfaction to participation.

Intervention groups

The three different groups studied are: The first group is patients who will receive only standard treatments of the national protocol for the treatment of Covid 19. (Control group) The second group, who will be receiving oxygen with a simple mask, will undergo peroneal and lung rehabilitation in addition to the national protocol treatments. The third group, who will be receiving oxygen with a reservoir mask, will undergo peroneal and lung rehabilitation in addition to the national protocol treatments.

Main outcome variables

spo2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210316050722N1**

Registration date: **2021-05-30, 1400/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-30, 1400/03/09**

Update count: **0**

Registration date

2021-05-30, 1400/03/09

Registrant information

Name

meysam elhami jadid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3226 4830

Email address

st-elhami.m@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of pulmonary rehabilitation and prone position on respiratory parameters in patients with COVID-19 admitted to non- specialized ward of Hajar hospital of Shahrekord; a double blind randomized clinical trial

Public title
Evaluation of the effects of lung rehabilitation and prone condition on respiratory parameters in patients with Covid-19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Covid-positive patients admitted to non-specialized wards From 18 to 75 years old Non-intubated and supported by oxygen therapy, No bed sores on shoulders, knees, and face, Estimated weight less than 100 kg
Exclusion criteria:
Patients with increased cerebral pressure Patients with increased intraocular pressure, Dissatisfaction with participation in the study,

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of participants to study groups (control group and two intervention groups one and two) will be done using random allocation software. Then, envelopes are prepared according to the number of people participating in the study and are recorded on the first envelope number one, the second envelope number 2, etc. Becomes. In this way, with the entry of each person, a special envelope is opened for that person and according to the option inside the envelope, the person is assigned to one of the control groups, intervention one or intervention two.

Blinding (investigator's opinion)
Double blinded

Blinding description
According to the table, people will be included in study one by one and a special code will be assigned to each group and members of each group so that patients keep blind about the type of intervention (one blind) and on the other side is blindness by a statistical specialist who will analyze the data without knowing the study groups

(blindness on the other side).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Parastar Aven.Hajar Hospital
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8816754633

Approval date
2021-02-23, 1399/12/05

Ethics committee reference number
IR.SKUMS.REC.1399.277

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
spo2

Timepoint
30 and 60 minutes after being in the prone position and also 60 minutes after the patient is in the supine position.

Method of measurement
Standard pulse oximetry device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The second group of standard treatment measures of the state oxygen protocol with a normal mask + 2 hours of prone position + 15 minutes of lung rehabilitation

Category

Rehabilitation

2

Description

Intervention group: Group 3 standard treatment measures of the state oxygen protocol with reservoir mask + 2 hours of prone position + 15 minutes of lung rehabilitation

Category

Rehabilitation

3

Description

Control group: Group 1 will only receive the standard treatments recommended in the national protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital, Shahrekord

Full name of responsible person

Akbar Soleimani

Street address

Parastar Aven

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

+98 38 3222 0016

Email

st-elhami.m@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mehraban Sadeghy

Street address

Parastar Aven

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

+98 38 3222 0016

Email

st-elhami.m@skums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Meysam Elhami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Parastar aven

City

Sahrekord

Province

Chahar-Mahal-va-Bakhtiari

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

2021-2022

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

I have not decided yet

From where data/document is obtainable

I have not decided yet

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

I have not decided yet

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Meysam Elhami

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Parastar Aven

City

Shahrekord

Province

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