

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of prone positioning in improving the oxygenation of patients with non-intubated & awake with lung involvement due to COVID-19 pneumonia

Protocol summary

Study aim

Evaluation of prone positioning in improving the oxygenation of patients with non-intubated & awake ARDS due to COVID-19 pneumonia.

Design

A clinical trial with a control group, with parallel groups, one-sided blind, will be performed on 60 patients

Settings and conduct

the study will be conducted in Rafsanjani Ali Ibn Abitaleb Hospital. patients are randomly divided into two groups A and B. Group A is control and no special intervention is done for them. Group B intervention includes patients who will be lying prone position for hours during the day and night. This change of position will be performed at least 2-3 times a day and will be measured the patient's saturation percentage frequently, ABG, c-reactive protein, lymphocyte and neutrophil count, pulse rate, and respiration per minute, before and after the change of position

Participants/Inclusion and exclusion criteria

inclusion criteria: 18-70 years old, confirmed COVID-19 disease, Saturation of Peripheral Oxygen < 90%, awake, able to prone position

Intervention groups

1. Intervention: patients that expose to prone positioning at certain times of day and night 2. control: Patients who do not lie prone positioning

Main outcome variables

Improve oxygenation of COVID-19 patients without the special facilities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210724051970N1**

Registration date: **2021-09-03, 1400/06/12**

Registration timing: **prospective**

Last update: **2021-09-03, 1400/06/12**

Update count: **0**

Registration date

2021-09-03, 1400/06/12

Registrant information

Name

Mohammad amin LOTFI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2295 6312

Email address

drlotfaimaim@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-21, 1400/06/30

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prone positioning in improving the oxygenation of patients with non-intubated & awake with lung involvement due to COVID-19 pneumonia

Public title

Evaluation of prone positioning in improving breathing of awake patients with dyspnea due to COVID-19

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 confirmed diagnosis of COVID-19 requiring non-invasive supplemental oxygen awake and able to do prone positioning
Exclusion criteria:
 pregnancy altered consciousness requiring intubation
 systolic blood pressure < 90 mmHg multi-organ failure

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
 Random sampling and Random allocation: In order to select individuals and assign them to two groups of intervention and comparison, three steps are performed in the form of access sampling, class allocation and simple random allocation, respectively. To do this, first, people with cardiovascular disease referred to Ali Ibn Abitaleb Hospital who meet the inclusion criteria are selected by available sampling. Since in some cases, despite the application of randomization program, there is also the possibility of heterogeneity in some of the initial features in the groups, so using the method Classification on Effective Variables Attempts to eliminate heterogeneity in groups are made before random allocation. In this study, age and sex are very important factors in observing education and improving oxygen delivery, so to ensure the equal distribution of these two variables in the two intervention and comparison groups, based on gender and age of people with four entry criteria, including men And females are more or less equal to 50 years, and then the samples in each class by a simple randomization method Using the Randomization.com website, which is available to researchers for free, they are divided into experimental and control groups. For example, in men over the age of 50, a list of random sequences such as the following sequence is generated and then, based on the number of people entering the study, people are divided into two groups of intervention and comparison.

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 Rafsanjan University of Medical Sciences

Street address

No. 10, Azadi Boulevard

City

Rafsanjan

Province

Kerman

Postal code

7716975334

Approval date

2021-06-07, 1400/03/17

Ethics committee reference number

IR.RUMS.REC.1400.059

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improve oxygenation

Timepoint

ABG measurement at the beginning of the study (before the intervention) and 3 days after it

Method of measurement

Blood draw from radial artery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Covid-19 patients referred to Ali Ibn Abitaleb Hospital in Rafsanjan, with a change in posture, lie on the abdomen at least two to three times a day (morning, noon and night, at least one hour after a meal for three consecutive days, and The percentage of oxygenation and other respiratory parameters in the form of each patient will be measured immediately

before the change of position, 1 hour after the start of the change of position.

Category

Rehabilitation

2

Description

Control group: particular intervention will not be done for them, and receive routine treatment.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb Hospital

Full name of responsible person

Ali Shamsi Zadeh

Street address

Imam Ali Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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Email

info@rums.ac.ir

Web page address

http://www.rums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Mohammad amin Lotfi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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