Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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'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)

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+98 21 2295 6312

Email address
drlotfimaim@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
Internal Medicine

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Full name of responsible person
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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