

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 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

dr.lotfaimaim@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

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Phone**

+98 34 3428 0001

**Email**

drloftimaim@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Ali Shamsi zadeh

**Street address**

Imam Ali Blvd

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Phone**

+98 34 3428 0038

**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

**Street address**

Mofatah Blvd, Aliibn abitalib hospital

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Phone**

+98 34 3428 0001

**Email**

drloftimaim@gmail.com

**Person responsible for scientific 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

**Street address**

Mofatah Blvd, Ali ibn abi talib hospital

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Phone**

+98 34 3428 0001

**Email**

drlotfimaim@gmail.com

**Person responsible for updating data**

**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

**Street address**

Mofatah Blvd, Ali ibn abi talib hospital

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Phone**

+98 34 3428 0001

**Email**

drlotfimaim@gmail.com

**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