

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Determining the effect of targeted oxygen therapy on the recovery outcomes of Covid-19 patients

#### Protocol summary

##### Study aim

Determining the effect of targeted oxygen therapy on the recovery outcomes of Covid-19 patients

##### Design

Clinical trial with control and intervention group, randomization, phase3 on 80 patients,40 patients in each group and Excel function rand function is used for randomization

##### Settings and conduct

After a visit to the emergency medicine physician and confirmation of COVID-19 by physician (measurement v/s variables, respiratory retention, six minutes walking, spo2 rate) cardiac symptoms and laboratory variables, the degree of pulmonary involvement, which is taken by CT scan of the lungs based on necessity and indication) and after confirming the inclusion criteria, the patient is placed in the intervention group. Patients with SPO2 <92% in the intervention group and undergoing oxygen therapy with a nasal catheter in the volume of 2-4 liters per minute to reach 92%-93 level of measuring variables before , 24 hours after,and at discharge, will be. Patients in the control group who reach 96% as nasal to spo2 above receive oxygen and are evaluated at three similar times at Baqiyatallah Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with positive PCR - Patients with mild involvement in CT scan - Patients with spo2 <92% Non-entry: Non-participation in the study by the patient - Patients who become ill during the study - Patients who have ICU admission

##### Intervention groups

Patients with lower spo2 than 92 per cent were placed in volume 2 - 4 litres per minute to reach the 92-93 % level and are measured at this level 92 % and are measured in this level of 92-93 hours (T1)and in the release time (T2).

##### Main outcome variables

BP, PR, RR, respiratory retention test; six minutes of walking test; spo2 rate; cardiac symptoms and laboratory variables; pulmonary involvement by CT scan

of the lungs based on necessity and indication

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211116053079N1**

Registration date: **2022-05-10, 1401/02/20**

Registration timing: **prospective**

Last update: **2022-05-10, 1401/02/20**

Update count: **0**

##### Registration date

2022-05-10, 1401/02/20

##### Registrant information

##### Name

Mojtaba Ferdosi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8755 0000

##### Email address

ferdosim732@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-01, 1401/03/11

##### Expected recruitment end date

2022-09-02, 1401/06/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Determining the effect of targeted oxygen therapy on the recovery outcomes of Covid-19 patients

### Public title

The effect of targeted oxygen therapy on the recovery outcomes of Covid-19 patients

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients with positive pcR Patients with mild lung involvement on CT scan Patients with spo2 Less than 92%

#### Exclusion criteria:

Failure to continue the intervention Patients who become ill during the project. Patients receiving ICU admission

### Age

From **18 years** old to **80 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Participant

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple randomization will be performed after the person participating in the study enters, ie after qualifying to participate in the trial and obtaining the informed consent of the participant in the research, as follows: 1- Creating a random sequence will be done with the help of a random number table 2- Central randomization will be used to hide random allocation.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

After enrolling in the study, patients did not know that they were in the intervention and control groups.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Baqiatallah University of Medical Sciences Ethical

Committee

#### Street address

South Shikh Bahaei street, Nosrati allay

#### City

Tehran

#### Province

Tehran

#### Postal code

1435915371

#### Approval date

2021-11-19, 1400/08/28

#### Ethics committee reference number

IR.BMSU.BAQ.REC.1400.037

## Health conditions studied

### 1

#### Description of health condition studied

covid-19

#### ICD-10 code

covid-19,v

#### ICD-10 code description

u07.1

## Primary outcomes

### 1

#### Description

SPo2

#### Timepoint

Upon arrival, 24 hours after, discharge

#### Method of measurement

Puls oximetry

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, oxygen therapy is given in a targeted manner (spo2 = 92-93%) as a nasal catheter in the volume of 2-4 liters per minute and the blood oxygen saturation level is maintained in the range of 92-93% and in three times Before the intervention, 24 hours later and the time of discharge of the consequences is checked. The measurement method is pulse oximetry and is performed until the intervention clears.

#### Category

Treatment - Other

### 2

#### Description

Control group: In the control group, oxygen is routinely or non-purposefully delivered as a nasal catheter. (spo2>

96%) and in the three desired times upon arrival, 24 hours later, the time of discharge of the consequences is checked. The method of measurement is by pulse oximetry.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Baqiyatallah Hospital

**Full name of responsible person**

Mojtaba Ferdosi

**Street address**

Baqiyatallah Hospital, after Sheikh Bahai, Mulla Sadra Street, Vanak Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 8126 7112

**Email**

Ferdosim732@gmail.com

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

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Dr. Gholam Hossein Ali Shiri

**Street address**

Baqiyatallah Hospital, after Sheikh Bahai, Mulla Sadra Street, Vanak Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 8126 7112

**Email**

ghalishiri@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Baqiyatallah University

**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**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Mojtaba Ferdosib

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Baqiyatallah Hospital, after Sheikh Bahai, Mulla Sadra Street, Vanak Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 8126 7112

**Email**

Ferdosim732@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Mojtaba Ferdosi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Baqiyatallah Hospital, after Sheikh Bahai, Mulla Sadra Street, Vanak Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 8126 7112

**Email**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Mojtaba Ferdosi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Baqiyatallah Hospital, after Sheikh Bahai, Mulla Sadra Street, Vanak Square

**City**

Tehran

**Province**

Tehran

**Postal code**

141556437

**Phone**

+98 21 8126 7112

**Email**

Ferdosim732@gmail.com

## 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**

All documents and data of the participants are after the informed consent and no name and details of the patient are entered.

**When the data will become available and for how long**

The access period is three months after the results are published.

**To whom data/document is available**

All professors of medical universities in the country

**Under which criteria data/document could be used**

Contribute to the advancement of science

**From where data/document is obtainable**

Ferdosim732@gmail.com

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

Communicate via email

**Comments**