

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Effects of Anionic Oxygen on O2 Saturation of COVID-19 Patients: A Multicenter Study

#### Protocol summary

##### Study aim

Rapid treatment of Covid-19 patients hospitalized and reduction of workload of medical staff

##### Design

In this cross-sectional study, 300 patients with Covid-19 admitted (in three hospitals) were randomly enrolled. Underlying variables such as age, sex, BMI, and type of underlying disease are extracted from patient records at the beginning of the study. The trial has a control group with parallel and double-blind groups. The patient's blood oxygen level is measured at the beginning of the study. The data obtained from this study are analyzed using SPSS software version 26 as well as Graph Pad software version 9.

##### Settings and conduct

patients after evaluation and confirmation of Covid 19 and having the inclusion conditions, Entered the study and the solution (H2O8) is used by three methods of inhalation ,Sublingual and rectal for used in the three mentioned hospitals.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Patient with Covid-19 and positive PCR  
Age over 18 years patient Hospitalized  
Exclusion criteria: patient or guardian unwillingness to continue cooperation

##### Intervention groups

The study was performed on 300 patients admitted to three hospitals of Shahid Labafinejad, Dr. Masih Daneshvari, and Emam Ali (AS) in Karaj, which were selected by simple random sampling and obtained with their informed consent. In this study, in which 100 patients were randomly selected from each center, the solution (H2O8) was used in three methods: inhalation, sublingual and rectal. 50 patients in all three methods of inhalation, sublingual and rectal, and 50 patients They will be in three groups as a control group

##### Main outcome variables

Evaluation and measurement of patients' blood oxygen levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190215042716N2**

Registration date: **2022-05-30, 1401/03/09**

Registration timing: **retrospective**

Last update: **2022-05-30, 1401/03/09**

Update count: **0**

##### Registration date

2022-05-30, 1401/03/09

##### Registrant information

##### Name

navid shafigh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8801 3378

##### Email address

n.shafigh@sbmu.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-10-22, 1400/07/30

##### Expected recruitment end date

2022-03-20, 1400/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Anionic Oxygen on O2 Saturation of COVID-19 Patients: A Multicenter Study

## Public title

Effects of Anionic Oxygen on O2 Saturation of COVID-19 Patients: A Multicenter Study

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patient with Covid-19 and PCR positive Age over 18 years Hospitalized

### Exclusion criteria:

No treatment of the patient or guardian to continue cooperation

## Age

From **18 years** old to **100 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **300**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients will be selected by simple random sampling from among patients admitted to three hospitals The equivalent of 300 Covid-19 patients will be included in this study (100 patients in each hospital by:50 patients in all three methods of inhalation, sublingual and rectal and 50 patients in three control groups)

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid beheshti University od Medical Sciences

##### Street address

Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

## Approval date

2022-04-24, 1401/02/04

## Ethics committee reference number

IR.SBMU.RETECH.REC.1401.036

## Health conditions studied

### 1

#### Description of health condition studied

Covid-19

#### ICD-10 code

U07.1

#### ICD-10 code description

Covid19 disease

## Primary outcomes

### 1

#### Description

blood oxygen levels

#### Timepoint

Every 2 hours

#### Method of measurement

Using a pulse oximeter

## Secondary outcomes

### 1

#### Description

LDH measurement

#### Timepoint

two hours

#### Method of measurement

Through a blood test

## Intervention groups

### 1

#### Description

Intervention group: Inhalation method of using solution (H2O8) in vials containing 5 ml,By nebulizer with particles less than 3 microns, every two hours for 60 hours that enters the patient's lungs.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Rectal method: 25 ml anal (rectal), used four times a day.(This method is used for patients with serious condition, including intubated patients)

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: Sublingual method: oral solution (H2O8) should be swallowed by the patient in the mouth for 2 to 4 minutes and then gently swallowed. Blood oxygen levels should be measured every two hours.

#### Category

Treatment - Drugs

### 4

#### Description

Control group: Patients in all three methods of inhalation, sublingual and rectal and 50 patients in three control groups  
Community Verified icon

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital the Educational ,  
Research and Treatment center

##### Full name of responsible person

Navid Shafigh

##### Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid  
Bahonar roundabout, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1956944413

##### Phone

+98 21 2712 2017

##### Email

N.shafigh@sbmu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Labbafinezhad Hospital

##### Full name of responsible person

Navid shafigh

##### Street address

9th Boostan, Pasdaran St.

##### City

Tehran

##### Province

Tehran

##### Postal code

1956944413

##### Phone

+98 21 2254 9010

##### Email

Lamc@sbmu.ac.ir

### 3

#### Recruitment center

##### Name of recruitment center

Emam Ali Hospital

##### Full name of responsible person

Navid shafigh

##### Street address

Vali-e-Asr st. , Azimiyeh,

##### City

karaj

##### Province

Alborz

##### Postal code

3154686695

##### Phone

+98 26 3252 7575

##### Email

Emamali@abzums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Navid Shafigh

##### Street address

Shahid Shahriari Square, Daneshjo Boulevard, Shahid  
Chamran Highway,

##### City

Tehran

##### Province

Tehran

##### Postal code

1983969411

##### Phone

+98 21 2990 2233

##### Email

n.shafigh@sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Navid Shafigh

**Position**

Associate

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Shahid Shahriari Square, Daneshjo Boulevard, Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Phone**

+98 21 2990 2233

**Email**

N.shafigh@sbmu.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Navid Shafigh

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Navid Shafigh

**Position**

Associate

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Email**

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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**

Yes - There is 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**

The whole potential data after being unidentifiable is published

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

1402

**To whom data/document is available**

Medical Society

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

Contributing to studies

**From where data/document is obtainable**

Email: n.shafigh@sbmu.ac.ir

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

Tho months

**Comments**