

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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 of 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

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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

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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

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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

Position

Associate

Latest degree

Subspecialist

Other areas of specialty/work

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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

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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