Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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 groupsCommunity Verified icon
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital the Edjucational , 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
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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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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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1983969411

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N.shafigh@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Navid Shafigh

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Subspecialist

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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