Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

Comparison of the effectiveness of Ozone therapy with conventional therapy in improving patient outcomes in Covid-19 patients

Protocol summary

Study aim
Evaluating the effectiveness of Ozone therapy in improving patient outcomes in COVID-19 patients

Design
A pragmatic, single-centre, parallel-group, nonblinded, phase 2 randomised controlled trial which will be conducted on 80 Covid-19 patients.

Settings and conduct
COVID-19 patients who visit Baqiyatallah clinic will be randomly allocated into two groups. After obtaining written informed consent for the oxygen-ozone therapy, patients of the treatment group will undergo Ozone Major Autohemotherapy either daily or twice daily, depending on the disease severity, for one to two weeks in addition to conventional treatments. Patients of the control group will just undergo conventional treatments. The severity of patient's symptoms, oxygen saturation and laboratory tests such as quantitative CRP will be recorded in all patients at baseline and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who have been diagnosed with Covid-19. Non-inclusion criteria: hypersensitivity to ozone; abnormal coagulation tests; abnormal thyroid function tests; G6PD deficiency; Pregnancy.

Intervention groups
Intervention group: Ozone therapy group. Patients will undergo a cycle of systemic oxygen-ozone therapy in addition to conventional treatments for COVID-19. Control group: Patients of the control group will not receive any treatments other than conventional treatments for COVID-19.

Main outcome variables
Quantitative CRP; Oxygen Saturation; dyspnea; fever; cough; diarrhea; headache; chills

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191125045492N2**
Registration date: **2020-04-18, 1399/01/30**
Registration timing: **prospective**

Last update: **2020-04-18, 1399/01/30**
Update count: **0**

Registration date
2020-04-18, 1399/01/30

Registrant information

Name
Ali Sarrafzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3324 7683

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ali_sarrafzadeh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-23, 1399/02/04

Expected recruitment end date
2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of Ozone therapy with conventional therapy in improving patient outcomes in Covid-19 patients

Public title
Effect of Ozone therapy in treatment of COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have been diagnosed with COVID-19
Exclusion criteria:
Patients with hypersensitivity to ozone Patients with abnormal thyroid function tests Patients with abnormal coagulation tests Patients with G6PD deficiency Pregnant or lactating women
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the individuals will be randomly allocated into two groups (Treatment and Control) by using the block randomization method. The procedure of randomization will be carried out by using the SPSS software and the block size will be 4. Allocation concealment will be carried out.
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 Baqiyatallah University of Medical Sciences
Street address
No. 2, South Sheikh Bahaei Ave.
City
Tehran
Province
Tehran
Postal code
1435912345
Approval date
2020-04-05, 1399/01/17
Ethics committee reference number
IR.BMSU.REC.1399.060

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.2
ICD-10 code description
COVID-19, virus not identified

Primary outcomes

1

Description
Quantitative CRP
Timepoint
Before and after the intervention
Method of measurement
Lab kit

2

Description
Oxygen Saturation
Timepoint
Before and after the intervention
Method of measurement
Pulse Oximetry

3

Description
Body's temperature
Timepoint
Before and after the intervention
Method of measurement
Thermometer

4

Description
Dyspnea
Timepoint
Before and after the intervention
Method of measurement
Subjective assessment of the patient and physical examination

5

Description
Cough
Timepoint
Before and after the intervention
Method of measurement
subjective assessment of the patient

6

Description
Diarrhea
Timepoint
before and after the intervention
Method of measurement
subjective assessment of the patient

7

Description
Headache
Timepoint
Before and after the intervention
Method of measurement
Subjective assessment of the patient

8

Description
Chills
Timepoint
Before and after the intervention
Method of measurement
Subjective assessment of the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the conventional treatments for Covid-19, patients will undergo a cycle of Ozone Major Autohemotherapy. In this method, a specific volume of patient's blood is drawn (100 to 200 cc in mild to moderate cases and 200 cc in severe cases). Then, a corresponding volume (100 to 200cc) of the oxygen-ozone gas mixture is added to the blood (initially with an ozone concentration of 35 micrograms/ml and gradually increasing it up to 45micrograms/ml in mild to moderate cases and up to 50micrograms/ml in severe cases). After mixing the blood with the gas mixture for at least 5 minutes with gentle rotating movements, the blood is reinfused to the patient. Mild to moderate cases will be treated daily for 4 days. Severe cases will be treated twice daily for at least 7 days.
Category
Treatment - Drugs

2

Description
Control group: Patients of this group, will just get the conventional treatments for COVID-19.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ozonetherapy Research Center, Baqiyatallah University of Medical Sciences
Full name of responsible person
Morteza Izadi
Street address
No. 2, South Sheikh Bahaei Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Dr. Gholamhosein Alishiri
Street address
Deputy of Research and Technology, Nosrati alley , South Sheikh Bahaei avenue, Mullasadra street, Vanak square
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1435916471
Phone
+98 21 8755 5250
Email
R.bmsu@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ali Sarrafzadeh
Position
General Practitioner on military service
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Sarrafzadeh house, No. 21, in front of Mellat park, Ahmadzade avenue, Ansari boulevard
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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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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