

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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)

###### Phone

+98 13 3324 7683

###### Email address

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**

Ozonotherapy 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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##### **Postal code**

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##### **Phone**

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##### **Email**

morteza\_izadi@yahoo.com

## **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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

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

+98 13 3324 7683

**Fax**

**Email**

ali\_sarrafazadeh@yahoo.com

## 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

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Sarrafazadeh house, No. 21, in front of Mellat park,  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Ali Sarrafzadeh

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

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**Phone**

## 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