

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 May 2021

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

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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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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

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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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Postal code

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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