

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the Effectiveness of Ozone Hemotherapy on the Respiratory Condition of Patients with Sever Covid with the Control Group

Protocol summary

Study aim

Evaluation of therapeutic effects of ozone chemotherapy on the respiratory status of patients with covid 19

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. For randomization, the block randomization method will be used. The method of assigning people to each block is using a table of random numbers (from top to bottom)

Settings and conduct

The present study is a clinical trial study on 60 patients with COVID who will be selected from two centers of Ziaian Hospital in Tehran and Imam Ali Hospital in Karaj. 30 patients undergo ozone chemotherapy for 10 sessions. The procedure is open label, meaning that patients will know which group they will be in.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age over 18 years; 2. Definitive Covid_19 disease (SARS_COV_2 PCR POSITIVE); 3. Patients who are hospitalized in the course of the disease; 4. Spo2 <90%; 5. CT scans of the lungs show evidence of involvement in Covid 19 disease; 6. Not being admitted to the ICU on the first visit to start ozone therapy -Exclusion criteria 1. Age less than 18 years; 2. Pregnancy; 3. Breastfeeding; 4. Intubation patient at the first visit to start ozone therapy; 5. Albumin below 3.5; 6. Presence of underlying diseases (liver, kidney, hyperthyroidism, hypothyroidism, heart disease);

Intervention groups

30 patients undergo ozone hemotherapy for 10 sessions. The patient's blood was taken in the first session 120 cc and combined with 120 cc of ozone gas and from the second session onwards 240 cc in the blood bag and with 240 Combine cc of ozone gas and inject it again into the patient. The first session is performed daily and the fifth session is performed every other day.

Main outcome variables

The effect of ozone chemotherapy on the respiratory status of patients with COVID

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200504047298N4**

Registration date: **2022-03-05, 1400/12/14**

Registration timing: **prospective**

Last update: **2022-03-05, 1400/12/14**

Update count: **0**

Registration date

2022-03-05, 1400/12/14

Registrant information

Name

Zeinab Siami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4602 2136

Email address

z.siami@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-15, 1400/12/24

Expected recruitment end date

2022-05-14, 1401/02/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Ozone Hemotherapy on the Respiratory Condition of Patients with Sever Covid with the Control Group

Public title

Investigating the effectiveness of Ozone Hemotherapy on the respiratory condition of patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Getting infected with covid 19 disease (SARS_COV_2 PCR POSITIVE) Patients who are hospitalized in the course of the disease Spo2 under 90% On the CT scan of lung, the evidences of covid 19 are presented Not being admitted at the ICU, on the first visit, at the start of ozone therapy

Exclusion criteria:

Age less than 18 years Pregnancy Breastfeeding Intubated patient on the first visit at the start of ozone therapy Album below 3.5 Presence of underlying diseases (liver, kidney, hyperthyroidism, hypothyroidism, heart disease)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Due to the total sample size, 60 people will be used to maintain the balance between the two groups in random blocking methods. Therefore, 10 blocks of 6 will be formed, and in each block, three in the intervention group and three will be in the control group. Allocating individuals to each block uses random numbers table (from top to bottom). The blinding is in the form of Open Label, that means patients will be informed of their groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

It is open label, meaning that, patients will be informed of their groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran National Committee for Ethics in Biomedical Research

Street address

No. 17, Abouzar St., After Abouzar Sq., Ziaeeian Hospital, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1366736511

Approval date

2022-02-11, 1400/11/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1331

Health conditions studied

1

Description of health condition studied

Covid 19

ICD-10 code

U07.1

ICD-10 code description

covid-19 diseaes

Primary outcomes

1

Description

Respiratory status

Timepoint

Daily

Method of measurement

With pulse oximetry device

Secondary outcomes

1

Description

Radiological changes in CT scan

Timepoint

Start of study, two weeks later

Method of measurement

Chest CT Scan

2

Description

mortality rate

Timepoint

Start of study, two weeks later

Method of measurement

Patient's clinical condition

3**Description**

Hospitalization rate in ICU

Timepoint

Start of study, two weeks later

Method of measurement

Evaluation of the patient's clinical condition

4**Description**

Inflammatory factors

Timepoint

Start of study, two weeks later

Method of measurement

blood test

Intervention groups**1****Description**

30 patients are undergoing Hemotherapy with ozone for 10 sessions. The patient's blood was taken at the first session to the amount of 120 cc and it is combined with 120 cc of gas. While from the second session, the amount of 240 cc in the blood bag was taken, and it combines with 240 cc ozone gas and it injects back into the patient. The first four sessions are daily, but from the fifth session, it is performed in the form of every other day.

Category

Treatment - Other

2**Description**

Control group: 30 patients with nearly similar conditions of the intervention group however only receive standard treatment.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ziaeeian Hospital

Full name of responsible person

Zeinab Siami

Street address

Abuzar Street, above Abuzar Square, Ziaeeian Hospital

City

Tehran

Province

Tehran

Postal code

1366736511

Phone

+98 21 5517 6810

Email

z.siami@abzums.ac.ir

2**Recruitment center****Name of recruitment center**

Emam Ali hospital

Full name of responsible person

Zeinab Siami

Street address

Emam Ali hospital, Azimeyeh, Karaj

City

Karaj

Province

Alborz

Postal code

3154686695

Phone

+98 26 3252 7576

Email

z.siami@abzums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zeinab siami

Street address

-

City

Tehran

Province

Tehran

Postal code

1366736511

Phone

+98 21 5517 6810

Email

z.siami@abzums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

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

Tehran University of Medical Sciences

Full name of responsible person

Zeinab Siami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Infection disease department, Emam ali hospital,
Azimieh, Karaj

City

Karaj

Province

Tehran

Postal code

1366736511

Phone

+98 21 4602 2136

Fax

Email

z.siami@abzums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zeinab Siami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Infection disease department, Emam ali hospital,
Azimieh, Karaj

City

Karaj

Province

Alborz

Postal code

1366736511

Phone

+98 21 4602 2136

Fax

Email

z.siami@abzums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zeinab Siami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Infection disease department, Emam ali hospital,
Azimieh, Karaj

City

Karaj

Province

Alborz

Postal code

1366736511

Phone

+98 21 4602 2136

Fax

Email

z.siami@abzums.ac.ir

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

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

Title and more details about the data/document

Article

When the data will become available and for how long

1402

To whom data/document is available

researchers

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access

data/document

-
Comments