Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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; ۲. Definitive Cavid_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 Abuzar Sq., Ziaeian 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
Ziaeian Hospital
Full name of responsible person
Zeinab Siami
Street address
Abuzar Street, above Abuzar Square, Ziaeian Hospital
City
Tehran
Province
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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
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Email
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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 departmant, Emam ali hospital, Azimieh,Karaj

City

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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

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

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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

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