Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the consequences of ozone therapy in hypoxia of oxygen-dependent patients affected by COVID-19 after discharge from the hospital

Protocol summary

Study aim
Investigating the effect of ozone therapy on pulmonary sequels in patients with COVID-19 and the resulting hypoxia
Design
Clinical trial with control and intervention groups, with parallel groups, without blinding, randomized, phase 2 on about 100 patients. Block randomization method will be used for randomization.
Settings and conduct
Place of study: Ozone therapy centers affiliated to BaqiyatAllah University located in Tehran and Najaf Abad. Study population: patients referred to the mentioned centers; Type of blinding: none
Participants/Inclusion and exclusion criteria
Inclusion criteria: Filling out the informed consent form; post COVID-19 oxygen dependent patients. Exclusion criteria: hypersensitivity to ozone; Albumin less than 3.4; Bleeding and coagulation disorders; Platelets less than 60,000; Uncontrolled hyperthyroidism
Intervention groups
Intervention group: The intervention of these patients will be with a therapeutic dose of 35-50 micrograms/ml with O2/O3 mixture based on the inflammatory factors and severity of pulmonary involvement at the time of referral. Control group: patients referred to the hospital/clinic who receive only standard treatment.
Main outcome variables
lung CT scan reports ,saturation of blood O2

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220814055690N1**
Registration date: **2024-03-22, 1403/01/03**
Registration timing: **prospective**

Last update: **2024-03-22, 1403/01/03**
Update count: **0**
Registration date
2024-03-22, 1403/01/03

Registrant information
Name
sina abbaspour
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-04-03, 1403/01/15
Expected recruitment end date
2024-05-19, 1403/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the consequences of ozone therapy in hypoxia of oxygen-dependent patients affected by COVID-19 after discharge from the hospital

Public title
Effect of ozone therapy in post COVID-19 lung sequels

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Filling out the informed consent form Post COVID-19 oxygen dependent patients
Exclusion criteria:
Hypersensitivity to ozone Albumin less than 3.4 Platelets less than 60,000 Bleeding and coagulation disorders Uncontrolled hyperthyroidism
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **206**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted (block randomization). Based on this method, the patients are categorized and equal number of participants are entered into the intervention and control groups at consecutive but equal time intervals. In this way, for example, one type of treatment is given to the first block, another type is given to the second, and again the first type is given to the third block and so on.
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
Baqiyatallah hospital, Sheikh Bahayi Ave., Mollasadra Ave., Vanak square
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2024-02-05, 1402/11/16
Ethics committee reference number
IR.BMSU.BAQ.REC.1402.095

Health conditions studied

1

Description of health condition studied
Post COVID fibrosis/ inflammatory lung disease
ICD-10 code
R91
ICD-10 code description
Abnormal findings on diagnostic imaging of lung

2

Description of health condition studied
COVID-19 disease
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
The percentage of improvement of pulmonary involvement in CT scan reports of patients
Timepoint
At the beginning of the study and 6 months after the received treatment
Method of measurement
CT scan report of patients

2

Description
Spirometry diagram
Timepoint
At the beginning of the study and 6 months after the received treatment
Method of measurement
Interpretation of spirometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients referred to ozone therapy centers affiliated to Baqiyatullah University located in Tehran and Najaf Abad, with a history of contracting COVID-19, who have been discharged from hospital with hypoxemia and oxygen dependency, will be included in the study. The therapeutic dose is 35-50 micrograms/mL with a volume of 120-240 cc of blood and its equivalent

O2/O3 mixture for 5-20 sessions, based on the inflammatory factors and severity of lung involvement and hypoxia at the time of referral, the exact amount of the dose and the number of sessions is selected. The first sessions will be daily and then alternate in the week.

Category

Treatment - Other

2

Description

Control group: This group receives standard treatment including prednisolone or pirfenidone. These patients were admitted to the hospital and referred to the relevant medical centers and received appropriate treatment and were included in the study under the name of control group. Normally, the dose of Pirfenidon for the first week is 267 mg daily, for the second week, 534 mg, and from the third week (maintenance treatment) 801 mg. Maintenance treatment is selected based on the condition and severity of the patient's involvement. Prednisolone is usually 1mg/kg daily, which can be changedbased on the patient.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Najafabad ozone therapy center

Full name of responsible person

Dr. Morteza Izadi

Street address

ozone therapy center, No.4, west 17 Shahrivar Ave., Najaf Abad

City

Isfahan

Province

Isfehan

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8581173441

Phone

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Email

Sina.Abbaspour75@gmail.com

2

Recruitment center

Name of recruitment center

Tehran Baqiyatollah ozone therapy center

Full name of responsible person

Dr. Morteza Izadi

Street address

Arya Physicians building, next to Baqiyatolla hospital, Mollasadra 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 Hossein Kachouyi

Street address

Vice President of Research and Technology, Baqiyatullah University, Molla Sadra Ave., Sheikh Bahayi Ave., Vanak Square, Tehran

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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

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Sina Abbaspour

Position

Substitute executor

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Morteza Izadi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

soldier

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available