

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Aug 2026

Evaluating the effectiveness of intravenous ozonized saline in treatment of severe COVID-19 disease: A randomized Control trial

Protocol summary

Study aim

Study of intra-venous ozonated normal saline on severe cases of COVID-19

Design

Randomised, superiority, parallel group trial, double blind, outcome assessment.phase 3. block randomization on 60 patient.

Settings and conduct

At the beginning of patients' referral to Razi Hospital in Ahvaz, if they have inclusion criteria, they will be included in the study. 400 ml of normal saline is ozonated by 40 micrograms per kilogram of patient body weight Ozone produced by the Medozon device. The concentration of ozone in normal saline with this method is 5 mic / ml and is injected into the patient within 15 to 30 minutes (80 to 120 drops per minute). This is done daily every morning for a week. All patients are monitored for general health status up to two weeks after the end of the protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria are Severe cases of Covid-19 with chest CT changes in the form of peripheral uni- or bilateral ground glass opacity(s) in combination with any of the below: RR greater than 24, O2 Sat less than 93%, BP less than 90/60, decreased level of consciousness. Exclusion criteria are G6PD Deficiency Coagulopathies and thrombocytopenia Hx of seizure Hypothyroidism Pancreatitis Hemophilias Acute alcohol poisoning Pregnancy and breast feeding Allergy to ozone and ozonated products

Intervention groups

The intervention group is patients who have received corona treatment according to the protocol, and in addition we give these people ozonated normal saline. The control group received corona treatment according to the protocol and normal saline that isn't ozonated

Main outcome variables

Lenth of hospital stay, need for ICU, duration of ICU stay, case fatality rate, PaO2/FiO2, need for mechanical

ventilation, duration of mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200730048253N1**

Registration date: **2020-08-08, 1399/05/18**

Registration timing: **prospective**

Last update: **2020-08-08, 1399/05/18**

Update count: **0**

Registration date

2020-08-08, 1399/05/18

Registrant information

Name

Najmeh Dareini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 5935

Email address

www.e24267s@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of intravenous ozonized saline in treatment of severe COVID-19 disease: A randomized Control trial

Public title

Evaluating the effectiveness of intravenous ozonized saline in COVID-19 disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Severe cases of Covid-19 with chest CT changes in the form of peripheral uni- or bilateral ground glass opacity(s) in combination with any of the below: RR greater than 24, O2 Sat less than 93%, BP less than 90/60, decreased level of consciousness.

Exclusion criteria:

G6PD Deficiency Coagulopathies and thrombocytopenia
Hx of seizure Hypothyroidism Pancreatitis Hemophilias
Acute alcohol poisoning Pregnancy and breast feeding
Allergy to ozone and ozonated products

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization with blocks with size of 6 and by the means of <https://www.sealedenvelope.com/>

Blinding (investigator's opinion)

Double blinded

Blinding description

Except of investigator, all of participants in the study wont be aware of the group treatment of the patient and they wont know the patient are in ozonated normal saline or normal saline alone

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

golestan st,

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2020-07-26, 1399/05/05

Ethics committee reference number

IR.AJUMS.REC.1399.363

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Duration of hospitalization

Timepoint

Daily Since hospitalization

Method of measurement

patient's file

Secondary outcomes

1

Description

Need for ICU

Timepoint

daily since hospitalization

Method of measurement

patient's file

2

Description

Duration of ICU stay

Timepoint

Daily since ICU stay

Method of measurement

Intervention groups

1

Description

Intervention group: The intervention group will receive the Iranian national protocol treatment of Covid-19 (which include any of the following, Hydroxychloroquine or Chlroquine Phosphate, Lopinavir-Ritonavir, Atazanavir-Ritanavir, IFN β -1a, IFN β -1b, Dexamethasone, Heparin or Enoxaparin) in addition to a thrice weekly ozonated normal saline. Thus, 400 ml of normal saline is ozonated by 40 micrograms per kilogram of body weight of the patient by Medozon device within ten minutes (ozone concentration in normal saline with this method is 5mic / ml) and within 15 minutes It is injected into the patient for 30 minutes (80 to 120 drops per minute). This is done daily every morning for a week

Category

Treatment - Other

2

Description

Control group: The control group will receive the Iranian national protocol treatment of Covid-19 (which include any of the following, Hydroxychloroquine or Chlroquine Phosphate, Lopinavir-Ritonavir, Atazanavir-Ritanavir, IFN β -1a, IFN β -1b, Dexamethasone, Heparin or Enoxaparin) and normal saline that is not ozonated. Taking normal saline is daily for a week.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

RAZI HOSPITAL

Full name of responsible person

Dr.Najme dareini

Street address

Felestin Blvd

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AHVAZ

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Khouzestan

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61965114941

Phone

+98 61 3392 5312

Email

e24267s@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. mohammad Badavi

Street address

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Ahvaz

Province

Khouzestan

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Phone

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Email

dr.mohammadbedoui@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

najme dareini

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

Street address

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Email

e24267s@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Shokrollah Salmanzadeh Ramhormozi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All related data will be provided upon completion of the study after disidentified IPD

When the data will become available and for how long

The related data will be indefinitely provided upon completion of the study.

To whom data/document is available

Relevant information will be provided to all interested parties for humanitarian study and research purposes upon completion of the study.

Under which criteria data/document could be used

On the condition that if any of the study methods (including study design and implementation method, measurement methods, etc.) are used the copyright law be observed and our study be cited.

From where data/document is obtainable

This will be provided upon completion of the study.

Contact: e24267s@gmail.com

What processes are involved for a request to access data/document

Contact via email: e24267s@gmail.com

Comments

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Najme Dareini

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

Street address

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Province

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