Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Patient's file

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
City
AHVAZ
Province
Khouzestan
Postal code
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
Golestan blvd
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Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8383
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
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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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salmanidmd@yahoo.com

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

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Ahvaz

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Postal code
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Phone
+98 61 3392 5312

Email
e24267s@gmail.com

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