

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Sep 2021

Investigation the effects medical Ozone Autohemotherapy on clinical and para clinical features of patients with Covid19

Protocol summary

Study aim

Determining the effect of Ozone Autohemotherapy on clinical and paraclinical features of patients with Covid19

Design

A controlled clinical trial, with parallel groups, single-blinded, randomized, phase 2 on 20 patients. RAS (Random Allocation Software) software will be used for randomization.

Settings and conduct

Twenty 20-60 years old patients with Covid19 who are admitted to the intensive care unit will be entered the study using the convenient sampling method and will be randomly allocated into two groups to receive 1) Ozone Autohemotherapy with conventional therapies or 2) conventional therapies. Autohemotherapy will be given three times a week for 10 times in total.

Participants/Inclusion and exclusion criteria

Documented Covid19 patients with age 20-60 years and admission to Intensive Care Unit

Intervention groups

Ozone Autohemotherapy, Injection of 100 ml of ozone at a concentration of 30micro / mL O2-O3 mixed with 100ml of patient's own heparinized blood will be given three times a week for a total of 10 times.

Main outcome variables

Complete Blood cell count and differential count, liver function tests and renal function test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043923N4**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Dawood Aghamohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 1928

Email address

aghamohammadi.d@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-25, 1399/02/06

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effects medical Ozone Autohemotherapy on clinical and para clinical features of patients with Covid19

Public title

Ozone Autohemotherapy in Covid19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Documented Covid19 patients With age 20-60 years

Admission to Intensive Care Unit

Exclusion criteria:

History of blood disorders History of liver failure History of renal failure History of chronic obstructive pulmonary disease

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

A block randomization method will be used to allocate participants to the groups with a 1:1 allocation using random allocation software (RAS). Similar sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants, data collection officials, those who evaluate the outcome and the person responsible for data analysis will be blinded to random allocation of participants to study groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

3692588521

Approval date

2020-04-13, 1399/01/25

Ethics committee reference number

IR.TBZMED.REC.1399.022

Health conditions studied

1

Description of health condition studied

Coronavirus infection

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Complete Blood cell count and differential count

Timepoint

Complete Blood cell count and differential count at the beginning of the study (before the intervention) and 7, 14 and 21 days after the start of ozone autohemotherapy

Method of measurement

Biochemical analysis

2

Description

Liver function tests

Timepoint

Liver function tests at the beginning of the study (before the intervention) and 7, 14 and 21 days after the start of ozone autohemotherapy

Method of measurement

Biochemical analysis

3

Description

Renal function tests

Timepoint

Renal function tests at the beginning of the study (before the intervention) and 7, 14 and 21 days after the start of ozone autohemotherapy

Method of measurement

Biochemical analysis

Secondary outcomes

1

Description

Mechanical ventilator weaning time

Timepoint

Mechanical ventilator weaning time during the study after the start of ozone autohemotherapy

Method of measurement

Comment by the treating physician

Intervention groups

1

Description

Intervention group: Major Autohemotherapy with common treatments. 100 ml of the patient heparinized blood is mixed with 100 ml of ozone at a concentration of 30micro /mL O2-O3 and injected again. These injections are given 3 times a week for a total of 10 times.

Category

Treatment - Drugs

2

Description

Control group: Common treatments

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Dawood Aghamohammadi

Street address

Emam Reza hospital, Golgasht Str., Azadi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

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3692588521

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+98 41 3334 4280

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Samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dawood Aghamohammadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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