Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Investigating Effect of Convalescent Plasma on COVID-19 Patients Outcome: A Clinical Trial

Protocol summary

Study aim
Determining effect of Convalescent Plasma on COVID-19 patients Outcome: A Randomised Clinical Trial

Design
The clinical trial has an intervention group without blinding and randomization

Settings and conduct
After the call for the donation of the convalescent plasma by the recently recovered patients, about 450 ml of the received plasma will be transferred to the COVID-19 patients hospitalized in the ICU of Imam Khomeini Hospital in Sari.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Recipient: 1- COVID-19 Patients 2- Consent to attend the study 3. Age 30 to 70 years 4- Don't be intubated 5- PaO2 / FiO2 is above 200 or Spo2 is greater than 85%. Donator: 1- Complete recovery from severe COVID-19 disease and hospital discharge 2- Consent to donate blood to the infected person 3- Age 30 to 60 years 4- Has normal CBC test results 5. Negative COVID-19 RT-PCR test Exclusion criteria: Recipient: 1. A history of hypersensitivity to blood transfusions or its products 2. History of IgA deficiency 3. Heart failure or any other factor that prevents the injection of of 500 ml plasma 4. Entering the intubation stage Donator: 1- Patients infected with blood-borne viral / infectious diseases 2 - Underlying heart disease, low or high blood pressure, diabetes, epilepsy, and anything that may prohibit blood donation. 3. Use of banned drugs for blood donation (eg, ethertinate, acitretin, aliotretinoin, isotretinoin, antiandrogens, NSAIDs, etc.) 4- Use of different drugs 5. Other prohibited donations based on blood transfusion standards

Intervention groups
Intervention to evaluate convalescent plasma transfer to COVID-19 patients admitted to ICU

Main outcome variables
1- 10-day mortality 2- 30-day mortality 3. Inflammatory factors 4- PaO2 / FiO2

General information

Reason for update
A change in English title

Acronym
COVID 19

IRCT registration information
IRCT registration number: **IRCT20181104041551N1**
Registration date: **2020-03-24, 1399/01/05**
Registration timing: **prospective**

Last update: **2020-04-12, 1399/01/24**
Update count: **1**

Registration date
2020-03-24, 1399/01/05

Registrant information

Name
Fateme Heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3336 1700

Email address
f.heydari@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-28, 1399/01/09

Expected recruitment end date
2020-05-20, 1399/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating Effect of Convalescent Plasma on COVID-19 Patients Outcome: A Clinical Trial

Public title
Investigating Effect of Convalescent Plasma on COVID-19 Patients Outcome: A Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
COVID-19 Patients Consent to attend the study Do not be intubated PaO2 / FiO2 above 200 or Spo2 above 85%

Exclusion criteria:
A history of hypersensitivity to blood transfusions or its products History of IgA deficiency Heart failure or any factor that prevent from getting 500ml of plasma Entering the intubation stage

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Vice-Chancellor for research, Mazandaran University of Medical Sciences, Moallem Sq.

City
Sari

Province
Mazandaran

Postal code
4817844718

Approval date
2020-03-23, 1399/01/04

Ethics committee reference number
IR.MAZUMS.REC.1399.7330

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Mortality

Timepoint
10 days and 30 days after intervention

Method of measurement
Measure of the number of deaths in a particular population, scaled to the size of that population, per unit of time.

2

Description
Inflammatory factors

Timepoint
Days 1, 3 and 7

Method of measurement
The enzyme-linked immunosorbent assay

3

Description
Partial pressure of arterial oxygen/Percentage of inspired oxygen

Timepoint
Days 1, 3, 7

Method of measurement
Partial pressure of arterial oxygen/Percentage of inspired oxygen

Secondary outcomes

1

Description
Length of hospitalization

Timepoint
End of study

Method of measurement
Day number

2

Description

Days of mechanical ventilation

Timepoint

End of study

Method of measurement

Day number

3

Description

Leukocyte and lymphocyte count

Timepoint

Days 1, 3, 7

Method of measurement

Complete blood count test

4

Description

CD3, CD4, CD8 cell count and CD4 / CD8 ratio

Timepoint

Days 1, 3, 7

Method of measurement

Flow Cytometry

5

Description

Function and changes of liver enzymes

Timepoint

Days 1, 3, 7

Method of measurement

Biochemical tests

6

Description

Cardiac enzyme function and changes

Timepoint

Days 1, 3, 7

Method of measurement

Biochemical tests

7

Description

Specific IgG

Timepoint

Days 1, 3, 7

Method of measurement

The enzyme-linked immunosorbent assay

8

Description

Radiological findings

Timepoint

Admitted time and day 14

Method of measurement

Computed tomography Scan and Chest X-Ray

Intervention groups

1

Description

Intervention group: COVID-19 patients who are hospitalized in the ICU, according to the blood type, receive about 450 ml of plasma received from COVID-19 patients who have recently recovered.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Educational Hospital, Sari

Full name of responsible person

Fatemeh Heidari

Street address

Imam Khomeini Educational Hospital, Razi St.

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Mazandaran

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4816633131

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Email

F.Heydari@mazums.ac.ir

Web page address

http://imamhospital.mazums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Professor Majid Saeedi

Street address

Vice-Chancellor for research, Mazandaran University of Medical Sciences, Moallem Sq.

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msaeedi@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Fatemeh Heidari

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Imam Khomeini Educational Hospital, Razi Sq.

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Person responsible for scientific inquiries

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Mazandaran University of Medical Sciences

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Assistant Professor

Latest degree
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Person responsible for updating data

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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
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
Not applicable

Title and more details about the data/document
SPSS data can be shared.

When the data will become available and for how long
Post publication

To whom data/document is available
Researcher

Under which criteria data/document could be used
Use for review study

From where data/document is obtainable
Corresponding author email

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

Comments