

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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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Sari

Province

Mazandaran

Postal code

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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Postal code

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Phone

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Email

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

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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Mazandaran University of Medical Sciences

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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