Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of plasma administration of COVID-19 survivors in patients with acute respiratory distress syndrome due to COVID-19

Protocol summary

Study aim

Determining the effect of plasma administration of COVID-19 survivors on one-month mortality of patients with acute respiratory distress syndrome during COVID-19 disease

Design

All hospitalized patients with acute COVID-19 respiratory distress syndrome who are eligible are placed in the intervention arm. In the intervention arm, in addition to first-line therapies such as corticosteroids, antibiotics, and hydroxychloroquine, patients will receive the survivor's plasma. Patients in the control arm are selected based on information recorded in the university registry system and will be similar to the control group in terms of age, sex, underlying disease and severity of respiratory disease. In the control arm, the necessary care and first-line therapies such as corticosteroids, antibiotics, and hydroxychloroquine will be prescribed according to the current symptoms. Due to the study conditions, blinding is not performed.

Settings and conduct

Imam Reza Hospital, Mashhad

Participants/Inclusion and exclusion criteria

Entry requirements: 1- Po2 / FIO2 ratio less than 300 2- The patient should be 18 to 75 years old Conditions of non-entry: 1-Intubated patient 2- Uncontrolled HTN 3. Advanced hepatic, heart or renal failure 4- COPD

Intervention groups

In the control group, patients receive all available supportive and specific therapies based on existing standards. In the intervention group, in addition to similar treatments in the control group, patients were given 600 cc of freshly survivors plasma.

Main outcome variables

1- The length of hospital stay in the ICU from the time of entering the study 2- The length of hospital stay from the time of entering the study 3- The need for mechanical ventilation from the time of entering the study 4 - Severity of the disease based on SOFA score 5- Severity of the disease based on Pao2 / Fio2 ratio

General information

Reason for update

According to the clinical condition of Covid 19 patients, the clinical trials execution committee in Mashhad University of Medical Sciences decided to perform this trial non-randomly so the control group with similar clinical conditions to the intervention group was selected from patients registered in the university registry system.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200409047007N1**
Registration date: **2020-04-12, 1399/01/24**
Registration timing: **prospective**

Last update: **2020-08-10, 1399/05/20**
Update count: **1**

Registration date

2020-04-12, 1399/01/24

Registrant information

Name

Mohsen Seddigh-Shamsi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 8818

Email address

seddighshamsim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-13, 1399/01/25

Expected recruitment end date
2020-08-15, 1399/05/25
Actual recruitment start date
2020-04-21, 1399/02/02
Actual recruitment end date
2020-05-31, 1399/03/11
Trial completion date
2020-06-27, 1399/04/07

Scientific title
The effect of plasma administration of COVID-19 survivors in patients with acute respiratory distress syndrome due to COVID-19

Public title
Effect of COVID 19 survivors plasma in COVID 19 patients with ARDS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Po2 / FIO2 ratio less than 300 despite receiving standard treatment The patient should be between 18 and 75 years old Normal IgA level Less than a week has passed since the patient entered the ICU
Exclusion criteria:
Uncontrolled HTN Advanced heart failure Systolic blood pressure less than 90 mm Hg COPD The patient is intubated Chronic renal failure with GFR less than 30 Advanced hepatic failure
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Actual sample size reached: **64**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Central University Building, University Street, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2020-04-06, 1399/01/18
Ethics committee reference number
IR.MUMS.REC.1399.055

Health conditions studied

1

Description of health condition studied
COVID-19 Disease
ICD-10 code
U07.02
ICD-10 code description
COVID-19 Disease

Primary outcomes

1

Description
mortality rate in 4 weeks from the time of entry into the study
Timepoint
The first month of entering the study
Method of measurement
Continuous clinical evaluation

Secondary outcomes

1

Description
The length of hospital stay in the ICU from the time of entering the study
Timepoint
Daily evaluation
Method of measurement
Clinical evaluation

Intervention groups

1

Description
Intervention group: In the intervention group, patients, in addition to the current standard treatments, also receive 600 cc survivor's plasma. For the preparation of fresh plasma products, survivors with 18 to 60 years old were

contacted and tested for CRP, CBC, HBS Ag, HCV Ab, HIV Ab, HTLV1 Ab, COVID 19 PCR and COVID 19 IgM & IgG antibody if they were without symptoms for at least 14 days. If all tests are normal, 600 cc plasma will be taken from them and are prescribed to patients in less than 12 hours. Survivors should have a positive initial PCR test for coronavirus, be male, or have no history of pregnancy if they are female. The donor and the patient must be the same in blood group.

Category

Treatment - Other

2

Description

Control group: Patients in the control arm are selected based on information recorded in the university registry system and will be similar to the control group in terms of age, sex, underlying disease and severity of respiratory disease. In the control arm, the necessary care and first-line therapies such as corticosteroids, antibiotics, and hydroxychloroquine will be prescribed according to the current symptoms.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Imam Reza Hospital

Full name of responsible person

Dr Abolghasem Allahyari

Street address

Department of Internal Medicine, Taqi abad Square, Mashhad

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9137913316

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allahyaria@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Central University Building, University Street, Mashhad, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Seddigh Shamsi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology Oncology

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Abolghasem Allahyari

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology Oncology

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Person responsible for updating data

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Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology Oncology

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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
After collecting and analyzing the data, the results will be made available to the public in the form of articles.

When the data will become available and for how long
After the publication of the article

To whom data/document is available
physicians

Under which criteria data/document could be used
There are no restrictions

From where data/document is obtainable
1- Dr Abolghasem Allahyari, Mashhad University of Medical Science 2- Dr Mohsen Seddigh Shamsi, Mashhad University of Medical Science

What processes are involved for a request to access data/document
Refer to the project supervisor

Comments