

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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- Po<sub>2</sub> / FIO<sub>2</sub> 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 Pao<sub>2</sub> / Fio<sub>2</sub> 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

##### City

Mashhad

##### Province

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##### Postal code

9137913316

##### Phone

+98 51 3859 8818

##### Email

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

##### Street address

Central University Building, University Street, Mashhad, Iran

##### City

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##### Province

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##### Phone

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##### Email

tafaghodim@mums.ac.ir

#### 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

Department of Internal Medicine, Taqi abad Square, Mashhad

##### City

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##### Province

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##### Postal code

9137913316

##### Phone

+98 51 3859 8818

##### Email

seddighshamsim@mums.ac.ir

## 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**

**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**

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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**