

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of therapeutic plasma exchange in patients with acute respiratory distress syndrome caused by Covid 19 disease

Protocol summary

Study aim

Evaluation of the effect of plasma replacement on one-month mortality of patients

Design

Clinical trial with retrospective control group, non-randomized, phase 2 on 42 patients. Matching will be done by propensity score and will be controlled in regression models.

Settings and conduct

This study will be performed in the Intensive care units of Imam Reza Hospital in Mashhad. 42 patients enter study based on inclusion and exclusion criteria. In 21 patients, in addition to standard treatments, plasmapheresis is performed. The other 21 patients will be selected from the ICU admitted patients from April 2020 until the time of study begins. Study objectives will be evaluated on days 0, 3, 7 and finally on day 30 after ICU admission. Regression models and propensity score calculation will be used to ensure the homogeneity of the intervention and control groups.

Participants/Inclusion and exclusion criteria

Patients over 15 years of age with definitive covid 19 based on positive PCR test, who have all of four criteria for acute respiratory distress syndrome and are available to enter the study with their (or their legal guardian) consent can enter the study. Patients with unstable hemodynamics or a history of myocardial infarction within 3 months before admission or history of allergies to blood products are not included in the study

Intervention groups

In the intervention group, in addition to standard treatments (but no IVIg, hemoperfusion and Tocilizumab) plasmapheresis done with fresh frozen plasma (FFP) at a rate of 10-20 cc per kg body weight, once a day for three days. In the control group, only standard treatments are used.

Main outcome variables

Death rate, length of stay in ICU, need for mechanical ventilation support, number of days of mechanical

ventilation and ARDS severity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200405046958N2**

Registration date: **2021-04-14, 1400/01/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-14, 1400/01/25**

Update count: **0**

Registration date

2021-04-14, 1400/01/25

Registrant information

Name

Mohammad Moeini Nodeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2742

Email address

moeininm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of therapeutic plasma exchange in patients with acute respiratory distress syndrome caused by Covid 19 disease

Public title
Evaluation of the effect of plasmapheresis in the treatment of Covid 19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patient must be definitive case of Covid-19 based on positive PCR test. The patient must have clinical and paraclinical criteria for acute respiratory distress syndrome (ARDS) The patient age must be over 15 years There must be the informed consent of the patient or his/her legal guardian
Exclusion criteria:
The patient has unstable hemodynamics The patient has a history of previous acute cardiac infarction in the last 3 months The patient has a history of allergies to blood products

Age
From **15 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
In this study,the control group will be retrospective and the previous data will be used, matching is done based on propensity score matching and this index is used in regression models to adjust for potential confounders.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical

Sciences
Street address
Ghaem Hospital, Ahmad Abad street
City
Mashhad
Province
Razavi Khorasan
Postal code
9186744163
Approval date
2020-05-12, 1399/02/23
Ethics committee reference number
IR.MUMS.REC.1399.223

Health conditions studied

1

Description of health condition studied

Covid 19 induced acute respiratory distress syndrome

ICD-10 code

U07.1

ICD-10 code description

Covid 19 virus identified

Primary outcomes

1

Description

death

Timepoint

first 30 days of hospital admission

Method of measurement

examination of vital signs

Secondary outcomes

1

Description

Disease severity

Timepoint

1st, 3rd and 7th day after ICU admission

Method of measurement

Use of SAPS3 and SOFA scoring systems

2

Description

ICU ward stay

Timepoint

Day 30 and 60 from hospital admission

Method of measurement

Patient visit

3

Description

Mechanical ventilation duration

Timepoint

All days of ICU admission

Method of measurement

Daily visit

4**Description**

Changes in CRP and Ferritin inflammatory markers

Timepoint

Days 0, 3 and 7 after ICU admission

Method of measurement

Serum levels of CRP and ferritin tests

Intervention groups**1****Description**

Intervention group: Patients who underwent plasmapheresis for 3 days in addition to routine treatment (Includes ventilation supportive care, serum therapy, treatment with heparin or enoxaparin, famotidine or pantoprazole, low-dose dexamethasone, remdesivir, atorvastatin, and antibiotics if needed)

Category

Treatment - Other

2**Description**

Control group: Patients who receive only the usual treatments listed.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital in Mashhad, ICU ward

Full name of responsible person

Mohammad Moeini Nodeh

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Imam Reza Hospital., Ibn Sina St

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MoeiniNM@mums.ac.ir

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Dadgar

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ghorayshi bilding., Daneshgah st.

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Vresaerch@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

Mohammad Moeini nodeh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology Oncology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

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

Title and more details about the data/document

Some of the data can be shared if the patients' privacy is respected and with the permission of the ethics committee.

When the data will become available and for how long

At the end of the study up to two years later.

To whom data/document is available

Any researcher who submits a written request to the corresponding author and can convince the researchers to share the information.

Under which criteria data/document could be used

Observance of research ethics, protection of participants' privacy and permission of the Medical Ethics Committee.

From where data/document is obtainable

Corresponding author.

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

Send email and provide sufficient reasons and permission of the Medical Ethics Committee.

Comments