Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 propencity 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
Street address
Imam Reza Hospital., Ibn Sina St
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9186744163
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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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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 updating data

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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