

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Effect of Plasmapheresis Treatment for the Management of Patients with Severe COVID19

Protocol summary

Study aim

Evaluation of the effectiveness of plasmapheresis treatment in patients with severe coronavirus with symptoms of pulmonary involvement

Design

Clinical trial with control group, with parallel, non-blind, randomized, phase 3 groups on 70 patients.

Settings and conduct

70 patients admitted to Seyed Al-Shohada and Al-Zahra Hospitals, Isfahan University of Medical Sciences with a definitive diagnosis of COVID-19 in 2021 will be included in the study in a non-probable manner based on inclusion criteria after obtaining informed consent. Patients in the control group will receive routine treatments for Covid disease. The case group, in addition to routine treatment, undergoes centrifugation plasmapheresis with FFP replacement.

Participants/Inclusion and exclusion criteria

Age over 18 years No pregnancy Do not get diseases that require a special treatment protocol Patient with cytokine storm Life-threatening illnesses such as respiratory failure, septic shock, dysfunction or multiple organ failure early ARDS Severe drug side effects leading to protocol changes. Acute coronary syndrome Severe sensitivity to FFP Uncontrolled heart failure Pulmonary embolism

Intervention groups

Divide into two equal case-control groups in parallel Patients in the control group will receive routine treatments for Covid disease. The case group, in addition to routine treatment, undergoes centrifugation plasmapheresis with FFP replacement

Main outcome variables

Reduce mortality rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200414047076N2**

Registration date: **2021-09-08, 1400/06/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-08, 1400/06/17**

Update count: **0**

Registration date

2021-09-08, 1400/06/17

Registrant information

Name

Elahe Nasri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 8006

Email address

elahe.nasri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Plasmapheresis Treatment for the Management of Patients with Severe COVID19

Public title

The assessment of the effect of plasmapheresis treatment for the management of sever COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years No pregnancy Do not get diseases that require a special treatment protocol Patient with cytokine storm Life-threatening illnesses such as respiratory failure, septic shock, dysfunction or multiple organ failure early ARDS

Exclusion criteria:

Age under 18 years pregnancy

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomized allocation will be done by some one who is not among the study researchers. The codes of participants will be entered in SPSS software which will allocated randomly to intervention or control groups.

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 Isfahan University of Medical Sciences

Street address

Hezar jarib

City

isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-06-26, 1399/04/06

Ethics committee reference number

IR.MUI.MED.REC.1400.195

Health conditions studied

1

Description of health condition studied

Covid-19,Plasmapheresis

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

The prevalence of mortality/morbidity

Timepoint

Three plasmaphereses with one or two days apart, examinations and tests in both groups every other day for two weeks and then every week for two weeks

Method of measurement

Patients' lab and file records

Secondary outcomes

1

Description

Determining the trend of O2 sat level changes in patients treated with plasmapheresis compared with the control group

Timepoint

daily

Method of measurement

pulse oximetre

2

Description

Determining the trend of LDH level changes in patients treated with plasmapheresis compared with the control group

Timepoint

daily

Method of measurement

Laboratory test

3

Description

Determining the trend of changes in ESR level in patients treated with plasmapheresis compared with the control group

Timepoint

daily

Method of measurement

Laboratory test

4

Description

Determining the trend of changes in CRP level in patients treated with plasmapheresis compared with the control group

Timepoint

daily

Method of measurement

Laboratory test

5

Description

Determining the trend of changes in ferritin level in patients treated with plasmapheresis compared with the control group

Timepoint

daily

Method of measurement

Laboratory test

6

Description

Determining the trend of changes in D-Dimer level in patients treated with plasmapheresis compared with the control group

Timepoint

daily

Method of measurement

ELISA

7

Description

Determining the trend of mortality rate changes in patients treated with plasmapheresis compared with the control group

Timepoint

daily

Method of measurement

patient file report

8

Description

Determining the mean length of hospital stay in patients treated with plasmapheresis compared with the control group

Timepoint

daily

Method of measurement

Questionnaire

Intervention groups

1

Description

The intervention group: The COVID-19 patients who will receive Centrifugation plasmapheresis which are replaced by FFP. The Plasmapheresis, Lab tests and clinical

examinations will be done every other day for treatment decision making. The treatment with plasmapheresis will be 3-5 times.

Category

Treatment - Other

2

Description

Control group: Patients will receive routine treatments for Covid disease

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital, Omid Hospital

Full name of responsible person

Elahe Nasri

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Kaveh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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research@mui.ac.ir

Grant name

Research of Isfahan University of Medical Sciences

Grant code / Reference number

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

Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Elahe Nasri
Position
Associate professor
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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
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
Yes - There is a plan to make this available
Title and more details about the data/document
Collect information in the form of articles
When the data will become available and for how long
One year
To whom data/document is available
all
Under which criteria data/document could be used
After publishing the article
From where data/document is obtainable
executor of plan
What processes are involved for a request to access data/document
Send your request via email

Comments

Due to the importance of treating patients with COVID

19, any guidance and questions will be answered by the facilitator