Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of the therapeutic role of plasmapheresis in patients with COVID-19 and its effect on serum levels of inflammatory factors

Protocol summary

Study aim

Evaluation of the therapeutic role of plasmapheresis in patients with COVID-19 and its effect on serum levels of inflammatory factors

Design

Clinical trial to evaluate the therapeutic effect of plasmapheresis on the severity of the disease and its effect on inflammatory factors in patients without control group and without blinding and randomization, phase 2, will perform on 45 patients with COVID-19 disease.

Settings and conduct

A total of 45 patients with COVID-19 admitted to the COVID-19 ward of Shahid Mohammadi Hospital in Bandar Abbas, who are candidates for plasmapheresis, are included in the study. Patients are recorded at the beginning of the study with their clinical history as well as laboratory and radiological findings. Patients then take 5 cc of peripheral blood once before plasmapheresis and once after three periods of plasmapheresis with an interval of one day. Finally, in addition to peripheral and clinical blood parameters according to the questionnaire used, ELISA technique will use to assess the serum levels of cytokines IL-6, IL-1β, TNF-α, IFN-γ.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Increased involvement of more than 50% of the lungs in CT scan - patient with symptoms of severe respiratory failure, patient in need or under mechanical ventilation, patient with multiple organ failure - inadequate response to antiviral and corticosteroid therapy and hypoxia during hospitalization. Exclusion conditions: Blood pressure below normal range - Coagulation disorders and low platelets below normal range.

Intervention groups

The intervention in this study is plasmapheresis in patients with severe COVID-19.

Main outcome variables

Blood oxygen level, body temperature, general condition of the patient, evaluation of serum levels of IL-6, IL-1β, TNF-α, IFN-γ, CRP, WBC, before and after plasmapheresis in patients with COVID-19.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200611047735N2**
Registration date: **2021-02-13, 1399/11/25**
Registration timing: **retrospective**

Last update: **2021-02-13, 1399/11/25**
Update count: **0**

Registration date

2021-02-13, 1399/11/25

Registrant information

Name

Amin Reza Nikpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 7192

Email address

nikpoora@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study of the therapeutic role of plasmapheresis in patients with COVID-19 and its effect on serum levels of inflammatory factors

Public title
The effect of Plasmapheresis in the treatment of patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
COVID-19 patients with positive Realtime PCR test for COVID-19 tachypnea> Respiratory Rate 30 per minute and dyspnea, Oxygen saturation lower than 88% and fraction of inspired oxygen/ PaO2 ratio lower to equal 300, and increased lung involvement by more than 50% on CT scan. Patient with symptoms of respiratory failure, patient in need or under mechanical ventilation, patient with multiple organ failure and patient with shock symptoms Presence of two positive inflammatory markers including: Ferritin greater than 1000 or CRP above 50 mg/dl or ´´ +++ ´´ or Lactate dehydrogenase greater than 1000 Lack of proper response to antiviral and corticosteroid therapy and hypoxia during hospitalization

Exclusion criteria:
Low blood pressure lower than normal range, which causes a further decrease in blood pressure during plasmapheresis. Coagulation disorders that cause bleeding during plasmapheresis. Decreased blood platelets below the normal range, which may increase bleeding during plasmapheresis.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences

Street address
Jomhouri Eslami Blvd

City
Bandar Abbas

Province
Hormozgan

Postal code
7919915519

Approval date
2020-09-26, 1399/07/05

Ethics committee reference number
IR.HUMS.REC.1399.343

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
Serum IL-6 levels

Timepoint
Before plasmapheresis and after the last stage of plasmapheresis

Method of measurement
ELISA technique

2

Description
Serum IL-1β levels

Timepoint
Before plasmapheresis and after the last stage of plasmapheresis

Method of measurement
ELISA technique

3

Description
Serum TNF-α levels

Timepoint
Before plasmapheresis and after the last stage of plasmapheresis

Method of measurement

ELISA technique

4

Description
Serum IFN-γ levels
Timepoint
Before plasmapheresis and after the last stage of plasmapheresis
Method of measurement
ELISA technique

5

Description
Clinical manifestation
Timepoint
Before plasmapheresis and after the last stage of plasmapheresis
Method of measurement
Clinical examination and completion of a questionnaire

6

Description
Inflammatory factors of peripheral blood
Timepoint
Before plasmapheresis and after the last stage of plasmapheresis
Method of measurement
Peripheral blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Plasmapheresis will be performed in 3 sessions at intervals of 24 to 36 hours based on the daily evaluation of the patient in the dialysis ward of Shahid Mohammadi Hospital in Bandar Abbas. Plasmapheresis will be performed by MSC + device is one of the types of apheresis devices of blood components including platelets, WBC, RBC, stem cells with high efficiency of plasmapheresis, with minimal platelet loss. Disposable single-needle sets will also used during plasmapheresis.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Mehdi Hassani Azad
Street address
Jomhouri eslami Blvd
City
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Postal code
7919915519
Phone
+98 76 3333 7192
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mehdi.hassaniazad@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
Street address
Jomhouri Eslami blvd
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teaghamolaei@gmail.com
Grant name
Grant code / Reference number
990342
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mehdi Hassani Azad
Position

Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for scientific inquiries

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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