

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

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

Protocol summary

TNF- α , IFN- γ , CRP, WBC, before and after plasmapheresis in patients with COVID-19.

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-1 β , 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-1 β ,

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)

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+98 76 3333 7192

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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-1 β 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

Jomhourī eslami Blvd

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Email

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

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Bandar Abbas

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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

Contact

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Position

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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