

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Plasmapheresis and plasma exchanges; usefulness in covid-19 critically ill patients

#### Protocol summary

##### Study aim

Determination of plasmapheresis effect and plasma replacement in patients with covid 19

##### Design

Use of plasmapheresis three times with 60% replacement of albumin 5% for one week in patients admitted to the treatment plan after reviewing the study selection criteria, and if the patient's blood pressure is allowed, plasma exchange with 100% replacement albumin 5% The duration of each plasmapheresis session is a maximum of 4 hours

##### Settings and conduct

Patients hospitalized in the intensive care unit who have not responded to normal treatment and have high interleukin 6 will be placed in the intensive care unit three times by plasmapheresis with a dialysis machine and will undergo plasma excision in case of normal vital signs.

##### Participants/Inclusion and exclusion criteria

1. age of patients ranged between 8 to 16 years  
2. COVID-19 positive  
3. interleukin above 6  
4. Patients hospitalized in the intensive care unit  
5. Increased respiration rate (be30 beats / min), difficulty breathing, cyanosis of the lips  
6. Oxygen saturation percentage  $\leq 93\%$   
7- Patients with covid-19 disease receiving antiretroviral therapy such as Favipiravir remdesivir, and kaletra have experienced an increase in interleukin and a cytokine storm during treatment.

##### Intervention groups

Our patients will undergo plasmapheresis three times to reduce interleukin and inflammatory factors and, if their hemodynamics allowed, plasma exchange will be done for them.

##### Main outcome variables

interleukin 6 oxygen saturation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150107020592N23**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

##### Registration date

2020-05-31, 1399/03/11

##### Registrant information

##### Name

Seyed Mohammad Reza Hashemian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2610 9944

##### Email address

iran.criticalcare@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-20, 1399/01/01

##### Expected recruitment end date

2020-06-20, 1399/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Plasmapheresis and plasma exchanges; usefulness in covid-19 critically ill patients

**Public title**

Plasmapheresis and plasma exchanges; usefulness in covid-19 critically ill patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

age of patients ranged between 8 to 16 years  
2.COVID-19 POSITIVE  
3. interleukin above 6  
4.Patients hospitalized in the intensive care unit  
5.Increased respiration rate (be30 beats / min), difficulty breathing, cyanosis of the lips  
6.Oxygen saturation percentage  $\leq 93\%$  .COVID-19 positive interleukin above 6  
Patients hospitalized in the intensive care unit  
Increased respiration rate (be30 beats / min), difficulty breathing, cyanosis of the lips  
Oxygen saturation percentage  $\leq 93\%$ , PaO<sub>2</sub> / FiO<sub>2</sub>  $\leq 300$  mmHg  
Patients with covid-19 disease receiving antiretroviral therapy such as Favipiravir ,remdesivir, and kaletra have experienced an increase in interleukin and a cytokine storm during treatment.

**Exclusion criteria:**

Patients treated with other interleukin-lowering methods, such as Actemra

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **15**

**Randomization (investigator's opinion)**

N/A

**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 Shahid Beheshti University of Medical Sciences

**Street address**

Yemen Street, Shahid Chamran Highway, Shahid Beheshti University of Medical Sciences, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Approval date**

2020-03-10, 1398/12/20

**Ethics committee reference number**

IR.SBMU.NRITLD.REC.1399.016

**Health conditions studied****1****Description of health condition studied**

Covid-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19 Disease

**Primary outcomes****1****Description**

oxygen percentage

**Timepoint**

One day before the procedure and one day and four days and seven days after the procedure

**Method of measurement**

Pulse Oximeter device

**2****Description**

interleukin 6 level

**Timepoint**

Before the procedure and one day and six days and seven days after the three-phase plasmapheresis

**Method of measurement**

Lab kit

**Secondary outcomes**

empty

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

Use plasmapheresis three times with 60% replacement of albumin 5% for one week in patients admitted to the treatment plan after reviewing the study selection criteria, and if the patient's blood pressure is allowed, plasma exchange with replacement with 100% albumin 5% duration of each session. Plasmapheresis maximum 4 hours and then measure interleukin-6 on days one, six and seven after plasmapheresis or plasma exchange

**Category**

Treatment - Devices

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Masih Daneshvari Hospital the Edjucational ,  
Research and Treatment center

**Full name of responsible person**

Dr Seyyed Mohamadreza Hashemian

**Street address**

Masih Daneshvari Hospital, Darabad Avenue, Shahid  
Bahonar roundabout, Tehran, Iran

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iran.criticalcare@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

dr.seyyad mohammadreza hashemian

**Street address**

End of niavaran, Darabad

**City**

Tehran

**Province**

Tehran

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**Phone**

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iran.criticalcare@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Reza Hashemian

**Position**

professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Masih Daneshvari hospital, Shahid Beheshti  
University of Medical Sciences, Tehran, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Reza Hashemian

**Position**

professor

**Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Reza Hashemian

**Position**

professor

**Latest degree**

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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

all of data after delete names are available

### When the data will become available and for how long

one year after research

### To whom data/document is available

all medical personnel

### Under which criteria data/document could be used

Help for education

### From where data/document is obtainable

Dr Smr hashemian

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

one month

### Comments