

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 years2.COVID-19 POSITIVE3. interleukin above 6 4.Patients hospitalized in the intensive care unit5.Increased respiration rate (be30 beats / min), difficulty breathing, cyanosis of the lips6.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 $\leq 93\%$,PaO2 / FiO2 ≤ 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

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2912 3100

Email

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

Postal code

1956944413

Phone

+98 21 2610 9512

Email

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

City

Tehran

Province

Tehran

Postal code

1957544413

Phone

+98 21 2610 9944

Fax

+98 21 2610 9944

Email

iran.criticalcare@yahoo.com

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

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Person responsible for updating data

Contact

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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