Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 ≤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
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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 ≤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 ≤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

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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

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End of niavaran,Darabad

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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

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

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Person responsible for scientific inquiries

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Seyed Mohammad Reza Hashemian

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Person responsible for updating data

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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