Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the efficacy and safety of Plasmapheresis in patients with Moderate to severe COVID-19

Protocol summary

Study aim
Investigating the efficacy and safety of Plasmapheresis in patients with moderate to severe COVID-19

Design
This study is a single-center, randomized, open-labeled, controlled and parallel .

Settings and conduct
Patients who is admitted to Baqiyatallah hospital and is meet the inclusion criteria, is entered to the study are randomly assigned into two groups of intervention and control.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmed diagnosis of COVID-19, with either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement,or RT-PCR confirmation;The patient/Legal guardian has written consciously and freely consent to participate in the study; The patient has moderate to severe Corona-Virus associated pneumonia; In the first 48 hours of hospitalization, the patient did not show an improving trend; In the first 48 hours after his/her inclusion into this study, there is no possibility of discharge from the patient's hospital. Exclusion Criteria: Multi organ failure; Pregnancy; Lactation.

Intervention groups
Intervention group: Plasmapheresis 3-5 session (based on clinical improvement), In addition to Amp. Methylprednisolone (500 mg day1, 250 mg day 2 and day3, IV) and routine treatment according to the latest national guideline for the treatment of new corona-virus Control group: Amp. Methylprednisolone (500 mg day1, 250 mg day 2 and day3, IV) and routine treatment according to the latest national guideline for the treatment of new corona-virus

Main outcome variables
Need to receive ICU service

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001165N58**
Registration date: **2020-05-27, 1399/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-27, 1399/05/06**
Update count: **1**

Registration date
2020-05-27, 1399/03/07

Registrant information

Name
Yunes Panahi

Name of organization / entity
Baqiyatallah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8821 1524

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-29, 1399/02/10

Expected recruitment end date
2020-06-30, 1399/04/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the efficacy and safety of Plasmapheresis in patients with Moderate to severe COVID-19

Public title
Investigating the efficacy and safety of Plasmapheresis in patients with Moderate to severe COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed diagnosis of COVID-19, with either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement,or RT-PCR confirmation. The patient/Legal guardian has written consciously and freely consent to participate in the study; The patient has moderate to severe Corona-Virus associated pneumonia; In the first 48 hours of hospitalization, the patient did not show an improving trend; In the first 48 hours after his/her inclusion into this study, there is no possibility of discharge from the patient's hospital;
Exclusion criteria:
Multi organ failure; Pregnancy; Lactation.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization method is used to randomized the patients. In this method, the number of people assigned to each group is usually almost equal. Blocks are formed based on the considered variables and within each block, half of the people are involved and half are considered as witnesses. The main goal in this method is to balance the number of participants in each group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Science
Street address
Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2020-04-26, 1399/02/07
Ethics committee reference number
IR.BMSU.REC.1399.119

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
Need to receive ICU service (occurrence of shock, resistant hypoxemia despite receiving oxygen via reservoir oxygen mask, GCS score drops below 12)
Timepoint
The patient is monitored every 6 hours, but the results are recorded daily in the checklist.
Method of measurement
Physical assessment

Secondary outcomes

1

Description
Mortality rate
Timepoint
30 days after including the study
Method of measurement
Physical assessment

2

Description
Length of hospitalization
Timepoint
The first day and the end of hospitalization
Method of measurement
The hospital record review

3

Description
Radiologic response

Timepoint
At the admission, before the discharge
Method of measurement
lung CT-SCAN

4

Description
Laboratory changes
Timepoint
Daily
Method of measurement
Blood sample, laboratory analysis

5

Description
Fever
Timepoint
Daily
Method of measurement
Thermometer

6

Description
Respiratory distress
Timepoint
Daily
Method of measurement
Clinical assessment

7

Description
Oxygen saturation without receiving oxygen supplement
Timepoint
It will be measured every 6 hours, but will be recorded daily
Method of measurement
Pulse-oxymetery device

Intervention groups

1

Description
Intervention group: Plasmapheresis 3-5 session (based on clinical improvement), In addition to Amp. Methylprednisolone (500 mg day1, 250 mg day 2 and day3, IV) and routine treatment according to the latest national guideline for the treatment of new corona-virus
Category
Treatment - Other

2

Description
Control group: Amp. Methylprednisolone (500 mg day1, 250 mg day 2 and day3, IV) and routine treatment according to the latest national guideline for the treatment of new corona-virusfor the treatment of new corona-virus
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah hospital
Full name of responsible person
Behzad Einollahi
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Baqiyatallah hospital, Mollasadra St., Vanak Sq., Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Gholamhosein Alishiri
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mohammad Rezapour
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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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