

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

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

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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-oxymetry 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-virus for 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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behzad.einollahi@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholamhosein Alishiri

Street address

Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran.

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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

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Yunespanahi@yahoo.com

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

General Practitioner

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parisa Kianpour

Position

Assistant

Latest degree

Specialist

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Pharmacotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Critical Care Pharmacotherapy

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Tehran

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