

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

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-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

**Street address**

Baqiyatallah hospital, Mollasadra St., Vanak Sq., Tehran, Iran.

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**Province**

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+98 21 8245 5393

**Email**

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

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

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**Email**

R.bmsu@yahoo.com

**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**

General Practitioner

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drrezapourmh@gmail.com

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

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Yunes Panahi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Critical Care Pharmacotherapy

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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

**Other areas of specialty/work**

Pharmacotherapy

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Pharmacy faculty, Tehran University of Medical  
Science, 16-Azar St., Enghelab Sq., Tehran, Iran.

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**Email**

parisa\_kianpour@yahoo.com

**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