

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The effect of pentaglobin in the treatment of critically ill patients with COVID-19

#### Protocol summary

##### Study aim

The effect of pentaglobin on patients with coronavirus

##### Design

covid-19 patients admitted to the intensive care unit and who had severe respiratory failure and lack of adequate response to treatment were included in the group, and a 7 mg.kg pentaglobin ampoule was gradually infused for 5 days. The general symptoms of patients and CT scans of patients were noted.

##### Settings and conduct

Patients admitted to the ICU who have respiratory failure and have not responded to treatment. They are selected and infused with pentaglobin ampule patients and patients' symptoms are noted.

##### Participants/Inclusion and exclusion criteria

Non-intubated patients Positive covid patients Patients over 18 years of age

##### Intervention groups

covid-19 patients admitted to the intensive care unit and who had severe respiratory failure

##### Main outcome variables

improve oxygenation; improve ct scans

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150107020592N27**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

##### Registration date

2020-06-15, 1399/03/26

##### 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

2020-06-21, 1399/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of pentaglobin in the treatment of critically ill patients with COVID-19

##### Public title

The effect of pentaglobin in the treatment of critically ill patients with COVID-19

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Covid patients Patients over 18 years Non-intubated patients

##### Exclusion criteria:

Patients with dissatisfaction

##### Age

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**Randomization (investigator's opinion)**

Not randomized

**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**

Masih Daneshvari Hospital the Edjucational ,  
Research and Treatment center.

**Street address**

Masih Daneshvari Hospital, Darabad Avenue, Shahid  
Bahonar roundabout, 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.1399.014

**Health conditions studied****1****Description of health condition studied**

covid-19

**ICD-10 code**

U07.1

**ICD-10 code description**

covid19 disease

**Primary outcomes****1****Description**

Improve oxygenation

**Timepoint**

0,1,2,3,7after treatment with cyclosporin

**Method of measurement**

Pulse oximeter

**2****Description**

Improve ct scan

**Timepoint**

Seven days after treatment

**Method of measurement**

CT scan unit

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: patient under pentaglobin treatment:  
Patients who have acute respiratory failure due to  
covid-19 and do not respond to antiretroviral therapy  
due to the unknown nature of the disease to reduce  
inflammatory cytokines in patients with slow pentaglobin  
injections within two hours of infusion and seven days  
continue and the general condition of patients and  
symptoms Patient and CT-scans are checked

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Masih Daneshvari Hospital

**Full name of responsible person**

Seyyed Mohammadreza Hashemian

**Street address**

Masih Daneshvari Hospital, Darabad, Niavaran Sq,  
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 Seyyed Mohamadreza Hashemian

**Street address**

Shahid Beheshti University of Medical Sciences,  
Tabnak Street, Shahid Chamran Highway, Tehran,  
Iran

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+98 21 2912 3100

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iran.criticalcare@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Vice Chancellor for Research and Technology, 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**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Masih Daneshvari Hospital, Darabad, Niavaran Street,  
Tehran, Iran

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**Postal code**

198396-3113

**Phone**

+98 912 111 9279

**Fax****Email**

smrhashemian@sbmu.ac.ir

**Web page address**

## 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

**Position**

Associate Professor

**Latest degree**

Subspecialist

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## Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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smrhashemian@sbm.ac.ir

**Web page address****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 patient information can be published after deleting the name

**When the data will become available and for how long**

It will take a month from the time of application

**To whom data/document is available**

All professors of medical universities in the country

**Under which criteria data/document could be used**

Help advance science

**From where data/document is obtainable**

professor hashemian in masih daneshvari hospital

**What processes are involved for a request to access data/document**

one month

**Comments**