

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of Convalescent Plasma as a Potential Therapy for COVID-19 infected patients

#### Protocol summary

##### Study aim

Evaluation of convalescent plasma therapy in the treatment of patients with COVID-19 disease

##### Design

Criteria of selection for plasma donors 1. The persons previously infected with COVID-19 and now recovered and discharged from hospitals 2. Donors should have normal laboratory tests according to guideline of Iran blood transfusion organization criteria 3. Voluntary consent to donate plasma 4. Maximum plasma volume of 650 ml Selection criteria for plasma recipients 1. Blood oxygen saturation <90% 2. Abnormal lung CT scan 3. Significant shortness of breath 4- Fever 5. Not improving in the next 48 hours 6- There is no possibility of discharge in the next 48 hours 7- consent

##### Settings and conduct

1. Convalescent plasma will be received from those recovering from COVID-19 disease previously hospitalized at Baqiyatallah; Masih Daneshvari; hospitals in Tehran and Shahid Beheshti hospital in Qom. 2- Convalescent Plasma received from volunteers will be infused to the patients with confirmed infection of COVID-19.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Blood oxygenation saturation <90% 2. Abnormal lung CT scan 3. Significant shortness of breath 4. Fever 5. Not improving in the next 48 hours 6. There is no possibility of discharge of patient in the next 48 hours 7. Patient consent Exclusion criteria 1. The patient should not be connected to a ventilator . 2. The patient has not given consent.

##### Intervention groups

Patients with confirmed COVID-19 disease

##### Main outcome variables

Reduction in all causes mortality; reduction of hospital stay

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200325046860N1**

Registration date: **2020-03-30, 1399/01/11**

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

Last update: **2020-03-30, 1399/01/11**

Update count: **0**

##### Registration date

2020-03-30, 1399/01/11

##### Registrant information

##### Name

Hassan Abolghasemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8126 3166

##### Email address

h.abolghasemi.ha@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-15, 1398/12/25

##### Expected recruitment end date

2020-08-20, 1399/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Convalescent Plasma as a Potential Therapy for COVID-19 infected patients

#### Public title

Convalescent Plasma therapy for COVID-19 Patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

COVID-19 infected patients with moderate to severe symptoms  
COVID-19 infected patients with severe symptoms non responding to other treatments

##### Exclusion criteria:

NO confirmed COVID-19 Disease

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 200

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

Since convalescent plasma therapy in patients with COVID-19 disease has been approved by FDA as a investigational modality and being used in some other countries such as China and due to lack of curative medicine for the disease, this project will be performed in Iran as treatment for the patients.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Medical Ethics Committee of Baqiyatallah University of Medical Sciences

##### Street address

Baqiyatallah University of Medical Sciences, Molla Sadra Street

##### City

Tehran

##### Province

Tehran

##### Postal code

1435915371

#### Approval date

2020-03-14, 1398/12/24

#### Ethics committee reference number

IR.BMSU.REC.1398.434

### 2

#### Ethics committee

##### Name of ethics committee

Ethical Committee of Higher Education and Research Institute of Blood Transfusion Medicine

##### Street address

Higher Education Institute of Blood Transfusion Medicine, Sheikh Fazlollah Nouri Highway, Shahid Hemmat Intersection , Next to Milad Tower

##### City

Tehran

##### Province

Tehran

##### Postal code

146651157

#### Approval date

2020-03-09, 1398/12/19

#### Ethics committee reference number

IR.TMI.REC.1398.031

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 Disease

#### ICD-10 code

U07.02

#### ICD-10 code description

COVID-19 Disease

## Primary outcomes

### 1

#### Description

Improving Respiratory function of patients

#### Timepoint

Every 24 hours

#### Method of measurement

Clinical and, Para-clinical

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Treatment group: Patients with confirmed COVID-19 infection who in addition to their current treatment will be infused with 500 ml convalescent plasma in 4 hrs.

#### Category

Treatment - Other

## 2

### Description

Control group: Patients hospitalized with COVID-19 disease who are receive routine treatment

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Baqiyatallah Hospital

**Full name of responsible person**

Dr Hassan Abolghasemi

**Street address**

Baqiyatallah Hospital, Molla Sadra Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 81261

**Email**

h.abolghasemi.ha@gmail.com

### 2

#### Recruitment center

**Name of recruitment center**

Shahid Beheshti Hospital, Qom, Iran

**Full name of responsible person**

Dr Ehsan Sharifipour

**Street address**

Shahid Beheshti Hospital, Shahid Beheshti Blvd

**City**

Qom

**Province**

Ghoum

**Postal code**

3716993456

**Phone**

+98 25 3285 2720

**Email**

ehsansharifipoor@yahoo.com

### 3

#### Recruitment center

**Name of recruitment center**

Firoozgar Hospital

**Full name of responsible person**

Dr Masoud Reza Sohrabi

**Street address**

Firoozgar Hospital, Karim Khan Street, Valiasr Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1593747811

**Phone**

+98 21 8214 1736

**Email**

sohrab\_r@yahoo.com

### 4

#### Recruitment center

**Name of recruitment center**

Masih Daneshvari Hospital

**Full name of responsible person**

Dr. Payam Tabarsi

**Street address**

Shahid Bahonar Street (Niavaran), Darabad

**City**

Tehran

**Province**

Tehran

**Postal code**

1956944413

**Phone**

+98 21 2712 2037

**Email**

payamtabarsi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Darmanara .Co

**Full name of responsible person**

Dr.Nariman Sadri

**Street address**

Saadat Abad, Sq. Culture, St. Moaree, Abshar Alley, Klmiya building

**City**

Tehran

**Province**

Tehran

**Postal code**

1997744417

**Phone**

+98 21 2214 0563

**Email**

n-sadri@darmanara.com

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

Yes

**Title of funding source**

Darmanara .Co

**Proportion provided by this source**

80

**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Other

## 2

### **Sponsor**

**Name of organization / entity**  
Iran Blood Transfusion Organization  
**Full name of responsible person**  
Dr Peyman Eshghi  
**Street address**  
hemmat Highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
146651155  
**Phone**  
+98 21 8860 1582  
**Email**  
peshghi64@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Iran Blood Transfusion Organization  
**Proportion provided by this source**  
20  
**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**  
Other

### **Person responsible for general inquiries**

#### **Contact**

**Name of organization / entity**  
Bagheiat-allah University of Medical Sciences  
**Full name of responsible person**  
Hassan Abolghasemi  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Microbiology  
**Street address**

Baqiyatallah University of Medical Sciences, Molla Sadra Ave  
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### **Person responsible for scientific inquiries**

#### **Contact**

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**Full name of responsible person**  
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Professor  
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### **Person responsible for updating data**

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Bagheiat-allah University of Medical Sciences  
**Full name of responsible person**  
Abbas Ali Imani Fooladi  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Microbiology  
**Street address**  
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**Email**

imanifouladi.a@gmail.com

## 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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

It will be published as an article

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

After printing the article

**To whom data/document is available**

All medical professionals

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

There is no restriction on access to information

**From where data/document is obtainable**

1- Dr. Hassan Abolghasemi, Baqiyatallah University of Medical Sciences 2- Dr Peyman Eshghi, IBTO

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

Refer to the project supervisor

**Comments**