

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of the effectiveness of intravenous infusion of human COVID-19 hyperimmune plasma with specific antibody titer in hospitalized patients with Covid-19: a randomized clinical trial

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of intravenous infusion of human COVID-19 hyperimmune plasma with specific antibody titer in hospitalized patients with Covid-19: a randomized clinical trial

##### Design

Case-control, 3 arm, parallel, single center, phase 3 clinical trial

##### Settings and conduct

This study will be performed in the lung diseases ward of Imam Khomeini Hospital in Tehran. Eligible patients with free and informed written consent will randomly assigned to one of the study groups and receive the relevant intervention.

##### Participants/Inclusion and exclusion criteria

Confirmed or suspected COVID-19 pneumonia based on PCR or pulmonary imaging; Presenting clinical symptoms of COVID-19 (fever, cough, dyspnea); O2 saturation equal or less than 93%; Age equal or more than 18 years old; The patient has informed and free written consent to participate in the study; Less than 7 days passed from the onset of clinical symptoms to the time of enrollment; The patient should not attend another clinical trial at the same time.

##### Intervention groups

Arm1: Human COVID-19 hyperimmune plasma with a specific antibody titer, volume 500ml, intravenous infusion over 4 hours; In addition to routine treatment based on the latest update of the national protocol. Arm2: Routine Human COVID-19 hyperimmune plasma, volume 500ml, intravenous infusion over 4 hours; In addition to routine treatment based on the latest update of the national protocol. Arm3: Routine treatment based on the latest update of the national protocol.

##### Main outcome variables

Requirement of receiving ICU care, mortality rate, requirement of mechanical ventilation, length of

hospitalization, NEWS2 score changes, Ordinal Scale changes, chest ct-scan score changes, side effects.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201004048922N1**

Registration date: **2020-10-10, 1399/07/19**

Registration timing: **prospective**

Last update: **2020-10-10, 1399/07/19**

Update count: **0**

##### Registration date

2020-10-10, 1399/07/19

##### Registrant information

##### Name

Hamidreza Abtahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2796

##### Email address

hrabtahi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-11, 1399/07/20

##### Expected recruitment end date

2021-02-18, 1399/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effectiveness of intravenous infusion of human COVID-19 hyperimmune plasma with specific antibody titer in hospitalized patients with Covid-19: a randomized clinical trial

**Public title**  
Evaluation of the effectiveness of intravenous infusion of human COVID-19 hyperimmune plasma with specific antibody titer in hospitalized patients with Covid-19: a randomized clinical trial

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Confirmed or suspected COVID-19 pneumonia based on PCR or pulmonary imaging; Presenting clinical symptoms of COVID-19 (fever, cough, dyspnea); O2 saturation equal or less than 93%; Age equal or more than 18 years old; The patient has informed and free written consent to participate in the study; Less than 7 days passed from the onset of clinical symptoms to the time of enrollment; The patient should not attend another clinical trial at the same time.

**Exclusion criteria:**  
Advanced renal or liver disease; Active cancer; Known Hypersensitivity reaction to Plasma-derived drugs; Pregnancy; Lactation; The patient may be excluded from the study during the first 48 hours.

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **75**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, the Block Randomization method will be used. To perform, by visiting the site [www.sealedenvelope.com](http://www.sealedenvelope.com), while entering the number of intervention groups, sample size, block size (which was selected according to the number of study groups, 6), a random list of patients in 3 groups will be obtained that this list will be used for random allocation of patients.

**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 Tehran University of Medical Sciences

##### Street address

Building No. 1 of the School of Medicine, Poursina St. North Door of the University, Ghods St., Enghelab Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417613151

#### Approval date

2020-09-09, 1399/06/19

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.436

## 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

Length of hospital stay due to covid-19

#### Timepoint

Daily until discharge or death

#### Method of measurement

Count the days of hospitalization from the time of admission to the hospital until discharge or death

## Secondary outcomes

### 1

#### Description

Mortality rate on day 28

#### Timepoint

Day 28 from enrollment

#### Method of measurement

Clinical assessment

## 2

### **Description**

Requirement rate of mechanical ventilation

### **Timepoint**

day 1 to 7

### **Method of measurement**

Clinical assessment

## 3

### **Description**

Requirement rate of receiving ICU care

### **Timepoint**

Day 1 to 7

### **Method of measurement**

Clinical assessment

## 4

### **Description**

The 7-point ordinal scale

### **Timepoint**

Day 1 and 7

### **Method of measurement**

Clinical assessment

## 5

### **Description**

National Early Warning Score 2 (NEWS2) changes

### **Timepoint**

Day 1 and 7

### **Method of measurement**

Clinical assessment and laboratory findings

## 6

### **Description**

Chest CT-scan score changes

### **Timepoint**

Day 1 and 28

### **Method of measurement**

Chest CT scan

## 7

### **Description**

Side effects

### **Timepoint**

Day 1 to 7

### **Method of measurement**

Clinical assessment

## **Intervention groups**

### 1

#### **Description**

Intervention group: Human COVID-19 hyperimmune plasma with a specific antibody titer, volume 500ml, intravenous infusion over 4 hours; In addition to routine treatment based on the latest update of the national

protocol.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group: Routine Human COVID-19 hyperimmune plasma, volume 500ml, intravenous infusion over 4 hours; In addition to routine treatment based on the latest update of the national protocol.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Control group: Routine treatment based on the latest update of the national protocol.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam khomeini Complex hospital

##### **Full name of responsible person**

Mohammadreza Salehi

##### **Street address**

Dr.Gharib St, End of Keshavrz Blvd.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

۱۴۱۹۷۳۳۱۴۱

##### **Phone**

+98 21 6693 9001

##### **Email**

salehi.mohamad3@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Mohammadali Sahraeiyan

##### **Street address**

6th floor, University Central Organization, corner of Quds St., Keshavarz Blvd.

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1417653761

**Phone**

+98 21 8163 3698

**Email**

vcr@tums.ac.ir

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Hamidreza Abtahi

**Position**

Associated Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pulmonary disease

**Street address**

Imam Khoemini Complex hospital, Dr.Gharib St., End of Keshavarz Blvd.

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**Province**

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**Postal code**

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**Phone**

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**Email**

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

Tehran University of Medical Sciences

**Full name of responsible person**

Hamidreza Abtahi

**Position**

Associated Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pulmonary disease

**Street address**

Imam Khomeini Complex hospital, Dr.Gharib St., End of Keshavarz Blvd.

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1419733141

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**Email**

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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**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Pharmacotherapy

**Street address**

Pharmacy faculty, Tehran University of Medical Science, 16 Azar St., Enghelab Ave.

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Tehran

**Province**

Tehran

**Postal code**

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**Phone**

+98 21 6695 4709

**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