

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Randomized, parallel-controlled and multi-center clinical study evaluating the efficacy and safety of convalescent plasma, in the treatment of patients with severe SARS-CoV-2 infection (COVID-19)

#### Protocol summary

##### Study aim

To evaluate the efficacy and safety of convalescent plasma in the treatment of patients with severe SARS-CoV-2 infection (COVID-19)

##### Design

Randomized, parallel-controlled group, multi-center clinical study

##### Settings and conduct

The study is performed among patients selected based on the guideline provided, at Hajar, Artesh Family, Artesh 501 and Besat Hospitals in Tehran by drug prescribing specialists.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Laboratory confirmed COVID-19 by PCR; Aged 18 to 70 years old; being inpatients; male or female; The clinical symptoms of severe or immediately life-threatening COVID-19. Non-inclusion criteria: Those who have history of allergy to blood products or plasma components and auxiliary materials (sodium citrat); The doctor believes that the patient is not suitable to participate in this trial because of their complications; Participation in another clinical trial; Taking any other medicine for COVID 19 treatment out of the study protocol.

##### Intervention groups

Intervention group: conventional therapy in combination with infusion of 200 -500 ml convalescent plasma (preferably in two infusions) . Control group: only conventional therapy

##### Main outcome variables

Clinical improvement within 14 days of admission (the overall condition of patient condition has been categorized in 6 condition in which death is point 6 and discharged is point 1. Two-point improvement or discharge will be considered as efficacy of the treatment).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200404046948N1**

Registration date: **2020-04-15, 1399/01/27**

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

Last update: **2020-04-15, 1399/01/27**

Update count: **0**

##### Registration date

2020-04-15, 1399/01/27

##### Registrant information

##### Name

neginsadat hosseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4487 2107

##### Email address

negiinsadaathm76@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-13, 1399/01/25

##### Expected recruitment end date

2020-06-20, 1399/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Randomized, parallel-controlled and multi-center clinical study evaluating the efficacy and safety of convalescent plasma, in the treatment of patients with severe SARS-CoV-2 infection (COVID-19)

**Public title**

Efficacy and safety of convalescent plasma in the treatment of COVID-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Laboratory confirmed COVID-19 by PCR Aged 18 to 70 years old Being inpatients The clinical severe or immediately life-threatening COVID-19 (Severe patients meet any of the following: Dyspnea, Respiratory frequency  $\geq$  30/min, Blood oxygen saturation  $\leq$  93% (in resting state), partial pressure of arterial oxygen to fraction of inspired oxygen ratio (PaO<sub>2</sub>/FiO<sub>2</sub>) < 300, and/or Lung infiltrates > 50% within 24 to 48 hours. Life-threatening disease is defined as: respiratory failure and need mechanical ventilation, septic shock, and/or multiple organ dysfunction or failure The patient or his/her legal guardian will sign the informed consent and participate voluntarily Accepting randomized allocation (allocating into any group) Being hospitalized before the end of the clinical trial and available for any follow-up

**Exclusion criteria:**

Those who has history of allergy to blood products or plasma components and auxiliary materials (sodium citrate) Critical conditions like multiple organ failure, and the estimated survival time is less than 3 days Severe congestive heart failure (CHF), or any other conditions in which plasma transfusion is contraindicated decided by researchers Any risk factor which may increase the risk of thrombosis, Pregnant or breastfeeding women Participation in another clinical trial Taking any other medicine for COVID 19 treatment out of the protocol The doctor believes that the patient is not suitable to participate in this trial

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization by computerized random number generation will be used. A list of sequentially number 1 to 60 will be created. This list will align numbers randomly by computer. Patients are randomly assigned to the experimental group (conventional treatment combined with convalescent plasma treatment group) or the control group (conventional treatment group) according to the numbers of this list.

**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**

AJA University of Medical Sciences

**Street address**

Etemadzadeh avenue; West Fatemi street

**City**

Tehran

**Province**

Tehran

**Postal code**

1411718541

**Approval date**

2020-03-28, 1399/01/09

**Ethics committee reference number**

IR.AJAUMS.REC.1399.007

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

Novel Coronavirus Pneumonia (COVID-19) Coronavirus (COVID-19)

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

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

Clinical improvement within 14 days of admission

**Timepoint**

everyday

**Method of measurement**

Clinical improvement is defined as the patient's admission status of 6 grade scale score reduced by 2 points or patient discharge. (Clinical improvement was defined as a 2-point reduction or discharge of a 6-point scale for patient admission status. The 6-point scale includes: 6 points: death; 5 points: hospitalization for ECMO and / or mechanical ventilation; 4 points: non-invasive admission Ventilation and / or high-flow oxygen

therapy; 3 points: hospitalization for oxygen therapy (but no high-flow or non-invasive ventilation is required); 2: points for hospitalization) Point1: discharge

## Secondary outcomes

### 1

#### **Description**

Mortality in a two groups during 14 days

#### **Timepoint**

everyday

#### **Method of measurement**

Examination and history

### 2

#### **Description**

Hospitalization Duration

#### **Timepoint**

Patient discharge day

#### **Method of measurement**

Examination and history

### 3

#### **Description**

ICU Hospitalization Duration

#### **Timepoint**

everyday

#### **Method of measurement**

Examination and history

### 4

#### **Description**

Invasive mechanical ventilation

#### **Timepoint**

everyday

#### **Method of measurement**

Examination and history

### 5

#### **Description**

ECMO duration

#### **Timepoint**

everyday

#### **Method of measurement**

Examination and history

### 6

#### **Description**

Proportion of PCR negative (3 AND 7 days after transfusion)

#### **Timepoint**

3 days and 7 days after injection

#### **Method of measurement**

PCR

### 7

#### **Description**

Clinical characteristics including, Fever, Respiratory frequency(RF) and PaO2/FiO2

#### **Timepoint**

everyday

#### **Method of measurement**

Examination and history

## Intervention groups

### 1

#### **Description**

Intervention group: patients in this group (Laboratory confirmed COVID-19 by PCR), will receive conventional therapy with Infusion of convalescent plasma, 200-500ml, two IV infusions during two consecutive days.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: Laboratory confirmed COVID-19 by PCR only receive conventional therapy

#### **Category**

Treatment - Other

## Recruitment centers

### 1

#### **Recruitment center**

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

Hajar hospital

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

Seyed Javad Hosseini Shokouh

##### **Street address**

Shahidbeheshti intersection, valiasr st, Tehran

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1411718546

##### **Phone**

+98 21 8871 0294

##### **Email**

rgsramin@yahoo.com

### 2

#### **Recruitment center**

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

Artesh Family hospital

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

Saeed Soleimani Meigouni

##### **Street address**

Kaj avenue; Shariati street

##### **City**

Tehran

**Province**  
Tehran  
**Postal code**  
16136  
**Phone**  
+98 21 7760 3076  
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dr.saeed.meigooni@gmail.com

### 3

#### **Recruitment center**

**Name of recruitment center**  
Artesh 501 hospital  
**Full name of responsible person**  
Ebrahim Hazrati  
**Street address**  
Etemadzadeh avenue; West Fatemi street  
**City**  
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**Province**  
Tehran  
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dr.hazrati.e@gmail.com

### 4

#### **Recruitment center**

**Name of recruitment center**  
Besat Hospital  
**Full name of responsible person**  
Mohammad Aminianfar  
**Street address**  
Hejrat street, Takhti three-way intersection  
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maminianfar@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**  
Artesh University of Medical Sciences  
**Full name of responsible person**  
Ramin Hamidi Farahani  
**Street address**  
West Fatemi AVE., Etemadzadeh st., Tehran  
**City**  
Tehran

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1411718541  
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+98 21 8833 7925  
**Email**  
rgsramin@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Artesh 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**

Artesh University of Medical Sciences

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

Ramin Hamidi Farahani

#### **Position**

President of Aja University of Medical Sciences

#### **Latest degree**

Specialist

#### **Other areas of specialty/work**

Infectious diseases

#### **Street address**

Etemadzadeh avenue; West Fatemi street

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#### **Province**

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#### **Postal code**

1411718541

#### **Phone**

+98 21 8609 6356

#### **Email**

Amir.salarian@gmail.c0m

## **Person responsible for scientific inquiries**

#### **Contact**

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

Artesh University of Medical Sciences

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

Ramin Hamidi Farahani

#### **Position**

President of Aja University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Neginsadat Hosseini Mohammadi

**Position**

دانشجوی پزشکی

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Farhangian avenue, Simon Bolivar boulevard

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1476619881

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negiinsaadathm76@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**

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**

After the publication of the article and removing confidential information like patients and hospital information, other information will be made available to researchers

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

After publication of the article

**To whom data/document is available**

Medical professionals

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

Medical professionals can access data for research purposes

**From where data/document is obtainable**

Refer to the email of the responsible author.

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

Official and academic email to the responsible author

**Comments**