

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 ≥ 30 /min, Blood oxygen saturation $\leq 93\%$ (in resting state), partial pressure of arterial oxygen to fraction of inspired oxygen ratio (PaO₂/FiO₂) <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

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2

Recruitment center

Name of recruitment center

Artesh Family hospital

Full name of responsible person

Saeed Soleimani Meigouni

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3

Recruitment center

Name of recruitment center
Artesh 501 hospital
Full name of responsible person
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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Ramin Hamidi Farahani
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West Fatemi AVE., Etemadzadeh st., Tehran
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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Latest degree

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Other areas of specialty/work

Infectious diseases

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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

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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