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)

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+98 21 4487 2107

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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 ≤ 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
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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
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Hejrat street, Takhti three-way intersection
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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Other areas of specialty/work
Infectious diseases

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Person responsible for updating data

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Position
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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