

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Use of convalescent plasma in the treatment of patients with severe COVID-19 pneumonia

Protocol summary

Study aim

There is no vaccine, drugs or approved treatment for 2019-nCoV because it is not well known and emerging. In this a prospective, phase II trial study, we intend to evaluate the safety and efficacy of using convalescent plasma for passive immunotherapy in patients with 2019-nCoV infection.

Design

This is a prospective, phase II trial study. Study will be done on patients who have severe pneumonia following 2019-nCoV infection and hospitalized in the ICU. Convalescent plasma will be used to treat patients.

Settings and conduct

Eligible patients who hospitalized in the ICU of Taleghani hospital will candidate for receiving convalescent plasma. Plasma donors will be evaluated based on inclusion and exclusion criteria. An about of 600-900 ml plasma will be obtained from each donor by apheresis. Eligible patients will receive 2 to 3 times ABO-compatible convalescent plasma in final volume of 250-300 ml with 1-day interval.

Participants/Inclusion and exclusion criteria

Inclusion criteria of plasma donor Recovery from 2019-nCoV infection according to clinical and laboratory criteria Negative RT-PCR test Negative results of serum/plasma for HBV, HCV, HTLV, HIV, and Syphilis Exclusion criteria of plasma donor Active respiratory infection symptoms: cough, dyspnea, oxygen requirements Fever during 3 days ago Inclusion criteria of recipient Positive 2019- nCoV infection by RT-PCR Respiratory > 30 beats/min SaO₂< 93% PaO₂ / FiO₂ ≤300 mmHg Exclusion criteria of recipient Co-infection with other respiratory viral infection

Intervention groups

convalescent plasma therapy in patients with COVID-2019

Main outcome variables

Size of lesion area by Chest CT scan Recovery of clinical symptoms such as fever and respiratory rate PaO₂/FiO₂

ratio All outcomes will be evaluated on day of 1, 4, 7,14, and 28 after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200416047099N1**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Abbas Hajifathali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1657

Email address

a.hajifathali@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-05, 1399/01/17

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Use of convalescent plasma in the treatment of patients with severe COVID-19 pneumonia

Public title

Plasma therapy in patient with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria of plasma donor (1-9) Recovery from 2019-nCoV infection according to clinical and laboratory criteria Pass the at least 28 days after hospital discharge Negative RT-PCR test (2 times with 48 h interval) Negative results of serum/plasma for HBV, HCV, HTLV, HIV, and Syphilis ABO, and RH antigens determination Fill informed consent to collect 650-1300 apheresis Inclusion criteria of recipient (11-15) Confirmed the diagnosis of nCoV infection by RT-PCR Respiratory > 30 beats/min SaO₂< 93% PaO₂ / FiO₂ ≤300 mmHg Fill informed consent

Exclusion criteria:

Exclusion criteria of plasma donor (2-13) Active respiratory infection symptoms: cough, dyspnea, oxygen requirements during 3 days ago History of Cardiac congestion, pulmonary hypertension, and other situation leading to apheresis failure Bleeding history and anti-coagulant agent therapy HBV vaccination during last week Receiving live-attenuated vaccines including BCG, yellow fever, measles, mumps, polio and typhoid fever during over the past three weeks Receiving IVIG injection, anti-tetanus, and other passive immunization over the past 6 weeks Small pox vaccination or contact with a person who receive Small pox vaccine Undefined loss weight > 4.5 kg, apheresis over the past three months Diagnosis of Dengue fever, Induced abortion, and blood transfusion over the past 6 months Exclusion criteria of recipient (11-14) Pregnancy, breast-feeding Patients with psychosis, severe systemic disease, and malignancy Patients with serious underlying disease for expample hematological disorder, cachexia, active bleeding, malnutrition, cardiovascular, renal, lung, and liver dysfunction Uncontrolled infection Patients who participated in other clinical trials Coinfection with HIV, Syphilis, Syphilis, tuberculosis, flu infection, adenovirus infection, and other respiratory viral infection

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice-chancellor in research affairs- shahid beheshti university of medical sciences

Street address

Vice-chancellor in research affairs, 5th floor, Block 2, shahid beheshti university of medical sciences, Next to Taleghani hospital, shahid a'rabi St, Yemen St, shahid Chamran Hwy

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-04-06, 1399/01/18

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.047

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

Coronavirus disease (COVID-19)

ICD-10 code

RA01.0

ICD-10 code description

The code for the confirmed diagnosis of COVID-19

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

Size of lesion area in lung

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

Chest CT scan

2**Description**

fever duration

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

termometer

3

Description

respiratory rate

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

the number of breaths per minute

4

Description

PaO2/FiO2 ratio

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

ventilator equipment

Secondary outcomes

1

Description

Nucleic acid virus

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

Real-time polymerase chain reaction

2

Description

anti-virus IgG antibody

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

Enzyme-linked immunosorbent assay

3

Description

Lymphocyte count

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

Cell counter

4

Description

CD3 cell count

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

Flow cytometry

5

Description

CD4+ cell count

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

Flow cytometry

6

Description

CD8+ cell count

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

Flow cytometry

7

Description

Mortality rate

Timepoint

After treatment

Method of measurement

Mortality rate formula

8

Description

Alanine aminotransferase enzyme level

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

AutoAnalyzer

9

Description

aspartate aminotransferase

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

AutoAnalyzer

10

Description

C-reactive protein

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

enzyme-linked immunosorbent assay

11

Description

Oxygen saturation

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

pulse oximeter

12

Description

Blood creatinine

Timepoint

On day of 1, 4,7,14, and 38 after plasma therapy

Method of measurement

Autoanalyzer

13

Description

Lactate dehydrogenase enzyme level

Timepoint

On day of 1, 4,7,14, and 38 after plasma therap

Method of measurement

Autoanalyzer

14

Description

Creatine kinase-MB

Timepoint

On day of 1, 4,7,14, and 38 after plasma therap

Method of measurement

Autoanalyzer

Intervention groups

1

Description

Intervention group: Convalescent plasma from patient who recovered from COVID-19,2 to 3 injections,injection volume of 250-300 milliliter every other day

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Abbas Hajifathali

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Velenjak St. , Shahid Chamran Highway, Tehran, Iran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice-chancellor in research affairs of Shahid Beheshti University of Medical Sciences

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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abbas hajifathali

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Taleghani hospital
Full name of responsible person
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Person responsible for updating data

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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