Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 trialsCoinfection 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

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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