

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

Evaluation of Convalescent Plasma as a Potential Therapy for COVID-19 infected patients

Protocol summary

Study aim

Evaluation of convalescent plasma therapy in the treatment of patients with COVID-19 disease

Design

Criteria of selection for plasma donors 1. The persons previously infected with COVID-19 and now recovered and discharged from hospitals 2. Donors should have normal laboratory tests according to guideline of Iran blood transfusion organization criteria 3. Voluntary consent to donate plasma 4. Maximum plasma volume of 650 ml Selection criteria for plasma recipients 1. Blood oxygen saturation <90% 2. Abnormal lung CT scan 3. Significant shortness of breath 4- Fever 5. Not improving in the next 48 hours 6- There is no possibility of discharge in the next 48 hours 7- consent

Settings and conduct

1. Convalescent plasma will be received from those recovering from COVID-19 disease previously hospitalized at Baqiyatallah; Masih Daneshvari; hospitals in Tehran and Shahid Beheshti hospital in Qom. 2- Convalescent Plasma received from volunteers will be infused to the patients with confirmed infection of COVID-19.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Blood oxygenation saturation <90% 2. Abnormal lung CT scan 3. Significant shortness of breath 4. Fever 5. Not improving in the next 48 hours 6. There is no possibility of discharge of patient in the next 48 hours 7. Patient consent Exclusion criteria 1. The patient should not be connected to a ventilator . 2. The patient has not given consent.

Intervention groups

Patients with confirmed COVID-19 disease

Main outcome variables

Reduction in all causes mortality; reduction of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200325046860N1**

Registration date: **2020-03-30, 1399/01/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-30, 1399/01/11**

Update count: **0**

Registration date

2020-03-30, 1399/01/11

Registrant information

Name

Hassan Abolghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 3166

Email address

h.abolghasemi.ha@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-15, 1398/12/25

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Convalescent Plasma as a Potential Therapy for COVID-19 infected patients

Public title

Convalescent Plasma therapy for COVID-19 Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

COVID-19 infected patients with moderate to severe symptoms
COVID-19 infected patients with severe symptoms non responding to other treatments

Exclusion criteria:

NO confirmed COVID-19 Disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Since convalescent plasma therapy in patients with COVID-19 disease has been approved by FDA as a investigational modality and being used in some other countries such as China and due to lack of curative medicine for the disease, this project will be performed in Iran as treatment for the patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, Molla Sadra Street

City

Tehran

Province

Tehran

Postal code

1435915371

Approval date

2020-03-14, 1398/12/24

Ethics committee reference number

IR.BMSU.REC.1398.434

2

Ethics committee

Name of ethics committee

Ethical Committee of Higher Education and Research Institute of Blood Transfusion Medicine

Street address

Higher Education Institute of Blood Transfusion Medicine, Sheikh Fazlollah Nouri Highway, Shahid Hemmat Intersection , Next to Milad Tower

City

Tehran

Province

Tehran

Postal code

146651157

Approval date

2020-03-09, 1398/12/19

Ethics committee reference number

IR.TMI.REC.1398.031

Health conditions studied

1

Description of health condition studied

COVID-19 Disease

ICD-10 code

U07.02

ICD-10 code description

COVID-19 Disease

Primary outcomes

1

Description

Improving Respiratory function of patients

Timepoint

Every 24 hours

Method of measurement

Clinical and, Para-clinical

Secondary outcomes

empty

Intervention groups

1

Description

Treatment group: Patients with confirmed COVID-19 infection who in addition to their current treatment will be infused with 500 MI convalescent plasma in 4 hrs.

Category

Treatment - Other

2

Description

Control group: Patients hospitalized with COVID-19 disease who are receive routine treatment

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Dr Hassan Abolghasemi

Street address

Baqiyatallah Hospital, Molla Sadra Street

City

Tehran

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Postal code

1435915371

Phone

+98 21 81261

Email

h.abolghasemi.ha@gmail.com

2

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Qom, Iran

Full name of responsible person

Dr Ehsan Sharifipour

Street address

Shahid Beheshti Hospital, Shahid Beheshti Blvd

City

Qom

Province

Ghoum

Postal code

3716993456

Phone

+98 25 3285 2720

Email

ehsansharifipoor@yahoo.com

3

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Dr Masoud Reza Sohrabi

Street address

Firoozgar Hospital, Karim Khan Street, Valiasr Square, Tehran, Iran

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1593747811

Phone

+98 21 8214 1736

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sohrab_r@yahoo.com

4

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Dr. Payam Tabarsi

Street address

Shahid Bahonar Street (Niavaran), Darabad

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Tehran

Province

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Postal code

1956944413

Phone

+98 21 2712 2037

Email

payamtabarsi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Darmanara .Co

Full name of responsible person

Dr.Nariman Sadri

Street address

Saadat Abad, Sq. Culture, St. Moaree, Abshar Alley, Klmiya building

City

Tehran

Province

Tehran

Postal code

1997744417

Phone

+98 21 2214 0563

Email

n-sadri@darmanara.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Darmanara .Co

Proportion provided by this source

80

Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

2

Sponsor

Name of organization / entity
Iran Blood Transfusion Organization
Full name of responsible person
Dr Peyman Eshghi
Street address
hemmat Highway
City
Tehran
Province
Tehran
Postal code
146651155
Phone
+98 21 8860 1582
Email
peshghi64@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran Blood Transfusion Organization
Proportion provided by this source
20
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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Hassan Abolghasemi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Microbiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Phone

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Email

imanifouladi.a@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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

It will be published as an article

When the data will become available and for how long

After printing the article

To whom data/document is available

All medical professionals

Under which criteria data/document could be used

There is no restriction on access to information

From where data/document is obtainable

1- Dr. Hassan Abolghasemi, Baqiyatallah University of Medical Sciences 2- Dr Peyman Eshghi, IBTO

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

Refer to the project supervisor

Comments