Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Ml 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
Province
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Postal code
1435915371
Phone
+98 21 81261
Email
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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
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Province
Ghoum
Postal code
3716993456
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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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Tehran
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Phone
+98 21 8214 1736
Email
sohrab_r@yahoo.com

4

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Dr. Payam Tabarsi
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Shahid Bahonar Street (Niavaran), Darabad
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Tehran
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1956944413
Phone
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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, KImiya 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
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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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Ph.D.
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1435915371

Phone

+98 21 81261

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