Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of Convalescent Plasma Therapy for COVID-19 Patients

Protocol summary

Study aim
Evaluation of Convalescent Plasma Therapy for COVID-19 Patients

Design
This study is a randomized clinical trial (RCT) of the prospective applied research type. Two groups of 20 patients with severe disease are included in the study as intervention and control groups. People under the age of 60 will be selected from patients with severe illness. In all respects, the control group includes age, sex, and drug use.

Settings and conduct
200 ml of plasma prepared from the blood bank of improved individuals with the same blood type as the target group is injected intravenously twice into patients in the intervention group who are hospitalized. Patients in the control group are not injected with blood plasma and receive the usual treatment protocol. In the days after treatment, clinical and laboratory symptoms, and the recovery process are compared between the intervention and control groups. Blinding is not predicted in the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with severe corona disease and age less than 60 years. Exclusion criteria: having a history of immune and/or other infectious diseases.

Intervention groups
The intervention group is injected with the same blood group twice and 200 ml each time. The control group does not receive plasma. The control group in all respects includes age, sex, drug use, and the group being matched.

Main outcome variables
The patient's age, Clinical protests, Mortality rate, Serological and molecular tests, Duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200503047281N1**
Registration date: **2020-07-25, 1399/05/04**
Registration timing: **prospective**

Last update: **2020-07-25, 1399/05/04**
Update count: **0**

Registration date
2020-07-25, 1399/05/04

Registrant information

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Farzaneh Fesahat
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Convalescent Plasma Therapy for COVID-19 Patients

Public title
Evaluation of Convalescent Plasma Therapy for COVID-19

Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 20 to 60 years old

Exclusion criteria:

People with a history of other immune, genetic or infectious diseases other than corona Individual suspended but negative for clinical standard covid-19 test

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done using a table of random numbers. In this method, all patients who meet the inclusion criteria are assigned a number from the file number and these numbers are randomly placed in the table of numbers. Then 20 numbers without the possibility of replacement as an intervention group and 20 people as the control group will be selected.

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

Ethics committee of Shahid Sadoughi University of MEdical Sciences

Street address

Daneshjoo Blv. reproductive immuology research center, Shadid Sadoughi University ,Yazd,Iran

City

yazd

Province

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8916188635

Approval date

2020-04-12, 1399/01/24

Ethics committee reference number

IR.SSU.REC.1399.001

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Percentage of patients discharged from the intensive care unit and hospital

Timepoint

Measurement of all standard clinical signs of the disease before the start of plasma therapy and after the start of each injection of plasma over specific intervals of up to one year (if surviving)

Method of measurement

Patient file information

Secondary outcomes

1

Description

Patient mortality rate

Timepoint

Recording the mortality rate for one year after starting plasma therapy

Method of measurement

Patient file information

Intervention groups

1

Description

Intervention group: 20 patients are in the severe stage of the disease who receive plasma therapy with intravenous injection dose twice (200 ml per dose) and in addition to routine medical care.

Category

Treatment - Drugs

2

Description

Control group: 20 patients admitted to the severe stage of the disease who did not receive plasma therapy and receive only routine medical care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd Shahid sadoughi hospital
Full name of responsible person
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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
Yazd 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
Yazd University of Medical Sciences
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Dr. Hossein Hadinedoushan
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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
Undecided - It is not yet known if there will be 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
All data can be published after coding and unidentifiable and privacy.

When the data will become available and for how long
after article publication

To whom data/document is available
All researchers specialize in related fields

Under which criteria data/document could be used
In order to use the results by the scientific community of the world, the information can be published after printing and by observing the coding and confidentiality of the participants in the study upon request.

From where data/document is obtainable
To the first author or the corresponding person of the published article through their email Dr. Hossein Hadi Nodoshan.hhadin2000@gmail.com

What processes are involved for a request to access data/document
The request and how to use the data must be explained by e-mail to the author responsible for the article, which will be received as soon as possible.

Comments