

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Aug 2022

### 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

##### Name

Farzaneh Fesahat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3628 5406

##### Email address

farzaneh.fesahat@gmail.com

##### 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

Yazd

##### Postal code

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**

Dr. Hossein Hadinedoushan

**Street address**

Shahid Sadoughi Hospital, Ibn Sina St., Shahid Ghandi Blvd., Safaieh, Yazd

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Masoud Mirzaei

**Street address**

Headquarters of Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Square, Yazd

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mmirzaei@ssu.ac.ir

**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

**Full name of responsible person**

Dr. Hossein Hadinedoushan

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

**Street address**

Reproductive Immunology Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

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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**