

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Oct 2020

### Immediate uses of convalescent covid-19 plasma in the treatment of new infected patients at the first day of hospitalization in a clinical trial

#### Protocol summary

##### Study aim

The purpose of this study is immediate uses of convalescent covid-19 plasma in the treatment of new infected patients at the first day of hospitalization in a clinical trial and evaluate the effectiveness of this type of treatment.

##### Design

Clinical trials have a control group, with parallel groups and phase 3 on 100 patients. The case group are 50 patients. The control group are 50 patients who are either not in randomization or not satisfied with receiving plasma.

##### Settings and conduct

The study is being conducted in Khuzestan province: Ahvaz, Razi Hospital and in Sistan and Baluchestan province: Zahedan, Bouali Hospital. After being hospitalized by the treating physician in hospital, treatment begins with the diagnosis and judgment of Covid-19. In the case group, plasma injection will be one of the first hospital treatment orders.

##### Participants/Inclusion and exclusion criteria

Symptomatic COVID-19 patients who are hospitalized and have Score>4 in terms of WHO Progression Scale will enter the study. COVID-19 patients who have Score<4 in terms of WHO Progression Scale and more than 24 hours passed from the hospitalization, wont enter the study.

##### Intervention groups

Convalescent plasma injection, a 500 cc unit will be injected to the case group within 4 hours in addition to antiviral and treatments available at the hospital. The control group treatment will only be antiviral and inpatient care.

##### Main outcome variables

The rate of reduction in the duration of hospital stay of patients; mortality reduction; requirement of artificial ventilation and entry into the ICU; The rate of achieve to minimum 2 point decrease in WHO clinical scale since plasma usage OR WHO score less than 3 (each achieved

first)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200525047562N1**

Registration date: **2020-06-14, 1399/03/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-24, 1399/04/04**

Update count: **1**

##### Registration date

2020-06-14, 1399/03/25

##### Registrant information

##### Name

Peyman Eshghi

##### Name of organization / entity

High institute for research & education in transfusion medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8860 1582

##### Email address

p.eshghi@ibto.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-25, 1399/03/05

##### Expected recruitment end date

2020-07-26, 1399/05/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Immediate uses of convalescent covid-19 plasma in the treatment of new infected patients at the first day of hospitalization in a clinical trail

**Public title**  
Treatment of Covid-19 patients with convalescent plasma

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Symptomatic COVID-19 patients who are hospitalized and have Score>4 in terms of WHO Progression Scale. The least reasons of hospitalization are dyspnea and/or SPO2<93% or RR>30 The intervention should be performed within the first 24 hours of hospitalization.  
**Exclusion criteria:**  
COVID-19 patients having Score<4 in terms of WHO Progression Scale. More than 24 hours passed from hospitalization.

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**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 the High Educational and Research Institute of Transfusion Medicine

##### Street address

High Educational and Research Institute of Transfusion Medicine, Shahid Hemmat HWY at Sheikh

Fazlollah Nouri HWY, next to Milad Tower

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1449613111

**Approval date**  
2020-05-20, 1399/02/31

**Ethics committee reference number**  
IR.TMI.REC.1399.003

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 disease

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Reduce at least 2 points on clinical signs or score less than 3, each earlier.

#### Timepoint

At the beginning of the study (before the start of the intervention) and day 4 of hospitalization, day 7 of hospitalization and discharge time.

#### Method of measurement

WHO Progression Scale

### 2

#### Description

length of hospital stay

#### Timepoint

Hospitalization time to discharge

#### Method of measurement

Counting days

## Secondary outcomes

### 1

#### Description

The rate of need for artificial ventilation and entry into the ICU

#### Timepoint

From hospitalization to discharge

#### Method of measurement

Percentage calculation

## Intervention groups

### 1

#### Description

Intervention group: Symptomatic COVID-19 patients who are hospitalized and have Score>4 in terms of WHO Progression Scale. Before 24 hours passed from the hospitalization. A 500 cc unit with blood group compatibility between receiver and donor is injected within 4 hours. In patients with grade 7 and above, a plasma unit can be re-injected after 24 hours. Plasma is obtained by apheresis from patients who have recovered from the covid-19 virus in blood transfusion centers.

#### Category

Treatment - Drugs

## 2

#### Description

Control group: The control group is a patient who is hospitalized with suspicion of Covid-19 but either not in randomization or not satisfied with receiving plasma.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bu Ali Hospital

##### Full name of responsible person

Hamid Reza Kouhpayeh

##### Street address

Bu Ali hospital, Shariati St

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9813617697

##### Phone

+98 54 3322 8102

##### Email

hkouhpayeh@yahoo.com

### 2

#### Recruitment center

##### Name of recruitment center

Razi hospital

##### Full name of responsible person

Mandana Pouladzadeh

##### Street address

Razi hospital, In front of the governorate, Palestine Street, Amaniye, Street, Amaniye, Street,

##### City

Ahwaz

##### Province

Khuzestan

##### Postal code

6133633366

##### Phone

+98 61 3333 5937

##### Email

Mandanapouladzadeh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

High Educational and Research Institute of Transfusion Medicine

##### Full name of responsible person

Mahtab Maghsoodlu

##### Street address

High Educational and Research Institute of Blood Transfusion Medicine, Shahid Hemmat HWY at Sheikh Fazlollah Nouri HWY, next to Milad Tower

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##### Email

maghsoodlu@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

High Educational and Research Institute of Transfusion Medicine

#### 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

Iran Blood Transfusion Organization

##### Full name of responsible person

Saeed Mohammadi

##### Position

Technical Deputy and New Technologies

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Hematology

##### Street address

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smohammadi@cina.tums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran Blood Transfusion Organization  
**Full name of responsible person**  
Peyman Eshghi  
**Position**  
Chief executive officer of the Blood Transfusion Organization of Iran  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
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P.eshghi@ibto.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran Blood Transfusion Organization  
**Full name of responsible person**  
Shamsi Okati  
**Position**  
Specialist physician  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
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14665-1157  
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**Email**  
shamsi.okati@yahoo.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

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

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

### Title and more details about the data/document

Information about the main and secondary consequences can be shared.

### When the data will become available and for how long

The access period will start 6 months after the results are printed.

### To whom data/document is available

Researchers working at academic and scientific institutes, as well as craftsmen, can apply to receive them.

### Under which criteria data/document could be used

The data/document can be used if the reasons of the request are determined. The type of analysis that will be performed on the delivered data are specified. Any type of data exploitation must be approved by the project supervisor.

### From where data/document is obtainable

He or she can refer to the High Educational and Research Institute of Blood Transfusion Medicine. Shahid Hemmat HWY at Sheikh Fazlollah Nouri HWY, next to Milad Tower Phone:0098 21 88601564 Website: ibto.ir

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

The High Educational and Research Institute of Blood Transfusion Medicine will receive and review the request, coordinate with the project manager, provide data files and inform to the applicant.

### Comments