

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of plasma therapy in the treatment of patients with COVID-19 infection. Randomized, open-label

#### Protocol summary

##### Study aim

Evaluation of the effects of plasma therapy on patient recovery and reduction of disease mortality

##### Design

Clinical trial with control group, with parallel groups, open-label, randomized, phase 3 on 58 patients. Simple randomization method was used as coding method. (A and B)

##### Settings and conduct

Patients referred to Hazrat Vali Asr Hospital in Birjand with COVID 19 infection whose disease has been confirmed by Real Time PCR molecular test or based on CT-Scan symptoms and whose infection is severe or life threatening. They were studied and randomly assigned to the case and control groups. The study was performed as an open-label study.

##### Participants/Inclusion and exclusion criteria

Willingness to participate in the study People over the age of 18 People with severe form of COVID-19 disease (shortness of breath, respiratory frequency  $\geq 30$  / min,, blood oxygen saturation  $\leq 93\%$ ,, partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $<300$ ,, percentage of pulmonary involvement more than 50 within 24-48 hours,)

##### Intervention groups

In the intervention group, patients receive 200 ml of convalescent plasma for one turn Improved plasma for one turn in addition to the standard treatment of Covid-19 (Hydroxychloroquine at a dose of 400 mg every 12 hours on the first day, then 200 mg every 12 hours for 14-17 days, or lupinavir-ritonavir at a dose of 400/100 mg for 12 hours for 7 days.). In control group, patients received standard Covid-19 treatment according to the national protocol.

##### Main outcome variables

Urea and creatinine levels, patient liver enzymes, patient oxygen saturation level, temperature, heart rate, systolic blood pressure and level of consciousness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210714051887N1**

Registration date: **2022-05-18, 1401/02/28**

Registration timing: **retrospective**

Last update: **2022-05-18, 1401/02/28**

Update count: **0**

##### Registration date

2022-05-18, 1401/02/28

##### Registrant information

##### Name

Masood Ziaee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3162 2430

##### Email address

dr.m.ziaee@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-21, 1399/06/31

##### Expected recruitment end date

2021-03-20, 1399/12/30

##### Actual recruitment start date

2020-09-21, 1399/06/31

##### Actual recruitment end date

2021-03-20, 1399/12/30

##### Trial completion date

2021-03-20, 1399/12/30

##### Scientific title

The effect of plasma therapy in the treatment of patients with COVID-19 infection. Randomized, open-label

#### Public title

The effect of plasma therapy in the treatment of patients with COVID-19

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Willingness to participate in the study  
People over the age of 18  
People with severe form of COVID-19 disease (shortness of breath, respiratory frequency  $\geq 30$  / min,, blood oxygen saturation  $\leq 93\%$ ,, partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $<300$ ,, percentage of pulmonary involvement more than 50 in 24-48 hours,)

##### Exclusion criteria:

-

#### Age

From **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **29**

Actual sample size reached: **29**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple randomization based on even and odd code

#### 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 birjand University of Medical Sciences

##### Street address

No. 28, Ghafari Ave., zakariyay razi Blvd, birjand University of Medical Sciences

##### City

birjand

##### Province

South Khorasan

#### Postal code

9717964151

#### Approval date

2020-09-15, 1399/06/25

#### Ethics committee reference number

IR.BUMS.REC.1399.253

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19 infection

#### ICD-10 code

J12.81

#### ICD-10 code description

Pneumonia due to SARS-associated coronavirus

## Primary outcomes

### 1

#### Description

Body temperature

#### Timepoint

On days two, three and 7 after hospitalization and receiving plasma

#### Method of measurement

Thermometer device

### 2

#### Description

Blood Saturated Oxygen Levels

#### Timepoint

On days two, three and 7 after hospitalization and receiving plasma

#### Method of measurement

Pulse oximeter

### 3

#### Description

C-reactive protein (CRP) Factor

#### Timepoint

On days two, three and 7 after hospitalization and receiving plasma

#### Method of measurement

Blood Test

## Secondary outcomes

### 1

#### Description

Duration of hospitalization of the patient

#### Timepoint

End of hospitalization or death of the patient

#### Method of measurement

By day

## 2

### **Description**

Heart rate

### **Timepoint**

On days two, three and 7 after hospitalization and receiving plasma (patient receives plasma treatment on the second day of hospitalization)

### **Method of measurement**

Monitoring device

## 3

### **Description**

Lung lesions on CT scan

### **Timepoint**

On days two, three and 7 after hospitalization and receiving plasma (patient receives plasma treatment on the second day of hospitalization)

### **Method of measurement**

Lung lesions with lung CT scan

## 4

### **Description**

D-dimer Factor

### **Timepoint**

On days two, three and 7 after hospitalization and receiving plasma (patient receives plasma treatment on the second day of hospitalization)

### **Method of measurement**

blood test

## **Intervention groups**

### 1

#### **Description**

Intervention group: Intervention group: In the intervention group, patients receive 200 ml of convalescent plasma for one turn Improved plasma for one turn in addition to the standard treatment of Covid-19 (Hydroxychloroquine at a dose of 400 mg every 12 hours on the first day, then 200 mg every 12 hours for 14-17 days, or lupinavir-ritonavir at a dose of 400/100 mg for 12 hours for 7 days.).

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: In this group, patients received standard Covid-19 treatment according to the national protocol (Hydroxychloroquine at a dose of 400 mg every 12 hours on the first day, then 200 mg every 12 hours for 14-17 days, or lupinavir-ritonavir at a dose of 100/100 mg for 12 hours for 7 days.).

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

valiasr hospital

##### **Full name of responsible person**

masood ziaee

##### **Street address**

No. 28. ghafari Ave., zakariyay razi blvd.birjand  
university of medical sciences

##### **City**

birjand

##### **Province**

South Khorasan

##### **Postal code**

9717964151

##### **Phone**

+98 56 3162 2430

##### **Email**

dr.ziaee@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Birjand University of Medical Sciences

##### **Full name of responsible person**

Masood Ziaee

##### **Street address**

No.28, ghafari Ave., Zakariyay Razi Blvd.Birjand  
university of medical sciences

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##### **Email**

dr.ziaee@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

masood ziaee

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Masood Ziaee

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

masood ziaee

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be 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**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

Not applicable

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

-

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

-

**To whom data/document is available**

-

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

-

**From where data/document is obtainable**

-

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

-

**Comments**