

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 ≥ 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 ≥ 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
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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

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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

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

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

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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