Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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 aopen-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 ≤ 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 studyPeople over the age of 18People with severe form of COVID-19 disease (shortness of breath, respiratory frequency ≥ 30 / min,, blood oxygen saturation ≤ 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
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Postal code
9717964151
Phone
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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
City
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South Khorasan
Postal code
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Phone
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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
Street address
No. 28, West, Ghafari Ave., Zakariyay Razi Blvd.Birjand university of medical sciences
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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dr.ziaee@gmail.com

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