Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison between the efficacy of intravenous immunoglobulin and convalescent plasma in improving the condition of patients with COVID-19: A randomized clinical trial

Protocol summary

Study aim
Comparison between the efficacy of intravenous immunoglobulin and convalescent plasma in improving the condition of patients with COVID-19

Design
clinical trial with control group- randomized- parallel groups

Settings and conduct
This study is a clinical trial with control group that will be performed in Vali-e-Asr Hospital in Birjand. 15 COVID19 patients will be divided into three groups by permuted block randomization: intravenous immunoglobulin therapy group (5 patients), convalescent plasma therapy group (5 patients), and control group(5 patients).

Participants/Inclusion and exclusion criteria
This study is a clinical trial with control group that will be performed in Vali-e-Asr Hospital in Birjand. 15 COVID19 patients will be divided into three groups by permuted block randomization: intravenous immunoglobulin therapy group (5 patients), convalescent plasma therapy group (5 patients), and control group(5 patients). All groups will receive common national protocol treatments. While one group will receive intravenous immunoglobulin in addition to the common national protocol (400 mg/kg/d) and the other group will receive common national protocol treatments twice and 200 cc each time in addition to the common national protocol.

Intervention groups
common national protocol treatments+common national protocol treatments common national protocol treatments+intravenous immunoglobulin

Main outcome variables
Lung involvement in X-ray and CT-scan, SPO2, LDH enzyme, viral load, acute phase protein, white blood cell count, ESR, length of hospital stay, duration of mechanical ventilation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200413047056N1**
Registration date: **2020-04-17, 1399/01/29**
Registration timing: **prospective**

Last update: **2020-04-17, 1399/01/29**
Update count: **0**

Registration date
2020-04-17, 1399/01/29

Registrant information

Name
malihe zangoue

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 56 3234 7036

Email address
mzangoue@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-18, 1399/01/30

Expected recruitment end date
2020-06-19, 1399/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between the efficacy of intravenous immunoglobulin and convalescent plasma in improving the condition of patients with COVID-19: A randomized clinical trial

Public title
Comparison between the efficacy of intravenous immunoglobulin and convalescent plasma in COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
RT-PCR Confirm the infection in the throat swab or sputum or lower respiratory tract samples. Sign the Informed Consent Form on a voluntary basis. Meet any of the following criteria for severe or critical ill conditions:Respiratory rate >=30/min; orRest SPO2<=90%; orPaO2/FiO2<=300mmHg; orRespiratory failure and needs mechanical ventilation; orMultiple organ failure and needs ICU monitoring

Exclusion criteria:

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization

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
Birjand University of Medical Sciences, Ghaffari st.

City
Birjand

Province
South Khorasan

Postal code
۹۷۱۷۸۵۳۵۷۷

Approval date
2020-04-13, 1399/01/25

Ethics committee reference number
IR.BUMS.REC.1399.008

Health conditions studied

1

Description of health condition studied
COVID-19 disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Lung involvement in X-ray and CT-scan, SPO2, LDH enzyme, viral load, acute phase protein, white blood cell count, ESR, length of hospital stay, duration of mechanical ventilation

Timepoint
from the start of the intervention for 12 days

Method of measurement
Blood and biochemical factors are measured using laboratory tests by an autoanalyzer. Pulmonary function indicators are measured by pulse oximetry and ABG.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the common national protocol, this group will receive convalescent plasma of recovered individuals twice and 200 cc each time.

Category
Treatment - Other

2

Description
Intervention group: In addition to the common national protocol, this group will receive intravenous immunoglobulin (400mg/kg/d).

Category
Treatment - Other

3

Description
Control group: This group will receive common national protocol.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali- e- Asr hospital
Full name of responsible person
Malihe Zangoue
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Vali- e- Asr hospital , Ghafari Street
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Sponsors / Funding sources

1

Sponsor
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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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
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Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available