

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; or Rest SPO₂ $\leq 90\%$; or PaO₂/FiO₂ ≤ 300 mmHg; or Respiratory failure and needs mechanical ventilation; or Multiple 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

9۷۱۷۸۵۳۵۷۷

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

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali- e- Asr hospital
Full name of responsible person
Malihe Zangoue
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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

Person responsible for general inquiries

Contact

Name of organization / entity
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Malihe Zangoue
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Latest degree
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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