Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of Intravenous immunoglobulin (IVIG) versus Kaletra (lopinavir and ritonavir) tablets in patients with acute respiratory infection (COVID-19): A clinical trial studies

Protocol summary

Study aim

Investigation of the effect of Intravenous immunoglobulin (IVIG) in comparison with Kaletra (lopinavir and ritonavir) tablets in patients with acute respiratory COVID-19 infection

Design

This study is a non-randomized, not blinded clinical trial with control group in phase 2 and sample size of 20.

Settings and conduct

This interventional study will be conducted as a prospective, Single-center trial. 20 patients with COVID-19 infection admitted to Bohlool hospital and have not responded to routine treatment, will be selected. All patients who meet the eligibility criteria with informed consent will receive IVIG or Kaletra. Patient's symptoms and their severity, clinical examinations and findings of chest CT scan will be evaluated before and after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Subjects (men or women) at least 18 years with definitive diagnosis with COVID-1; Having one of the factors of decrease in consciousness level; hypoxemia; hypercapnia; Increased lung involvement despite treatment; Informed consent.Exclusion criteria: Sensitivity to IVIG; Pregnancy; Breastfeeding; IgA deficiency.

Intervention groups

Intervention group will receive a standard regimen for COVID-19 plus intravenous immunoglobulin (IVIG),They will receive 400 mg/kg/day of IVIg in 3 doses (max=25 g). Control group will receive Kaletra (200/50) two tablet every 12 hr for 7-14 days.

Main outcome variables

Improvement the radiologic and laboratory parameters; necessity to ICU admission; duration of ventilation; duration the hospitalization; the mortality rate; SpO2.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200418047116N1**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Negar Shafaei bajestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5723 6833

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Intravenous immunoglobulin (IVIG) versus Kaletra (lopinavir and ritonavir) tablets in patients with acute respiratory infection (COVID-19): A clinical trial studies

Public title
The effect of Intravenous immunoglobulin on COVID-19 infection

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Positive PCR for COVID -19 Informed consent for inclusion Hypoxemia not responsive to oxygen therapy Loss of consciousness (GCS<=14) Hemodynamic instability Hypercapnia Extent of pulmonary involvement Non-use estrogen-containing compounds Non-be pregnant or breastfeeding

Exclusion criteria:
Sensitivity to IVIG IgA deficiency history Allergic reaction during IVIG injection

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Gonabad University of Medical Sciences

Street address
Dr.Mehdizade Blvd.

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Approval date
2020-04-06, 1399/01/18

Ethics committee reference number
IR.GMU.REC.1399.009

Health conditions studied

1

Description of health condition studied
COVID-19 disease

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
Pulmonary manifestations

Timepoint
before and after treatment

Method of measurement
Computed Tomography scan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: intravenous immunoglobulin (IVIG), brand name Intratect ®, 400 mg/kg/day in 3 doses will be administered by slow intravenous infusion.

Category
Treatment - Drugs

2

Description
Control group: Lopinavir/ritonavir, brand name Kaletra®, two tablet of 200/50 mg dose every 12 hours will be administered orally.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Bohlol Hospital

Full name of responsible person
Najme Davoodian

Street address
Vahdat Blvd.,Saadi St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Gonabad 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
Gonabad University of Medical Sciences
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Negar Shafaei Bajestani
Position
Assistant Professor
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Person responsible for updating data

Contact
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Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

Data can be accessible 6 months after results are published.

To whom data/document is available

The researchers in university and other scientific institutes.

Under which criteria data/document could be used

Help in managing of patients.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments