Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the efficacy of intravenous immunoglobulin (IVIg) in patients with severe COVID-19 (Before intubation phase) who have not responded to treatment with the standard three-drug protocol (hydroxychloroquine / chloroquine + lupinavir / ritonavir + ribavirin)

Protocol summary

Study aim

Evaluation of the efficacy of intravenous immunoglobulin (IVIg) in patients with severe COVID-19 (Before intubation phase) who have not responded to the standard three-drug protocol (hydroxychloroquine / chloroquine + lupinavir / ritonavir + ribavirin).

Design

Clinical trial with no control group, not blinded and not randomized

Settings and conduct

This study will be conducted on 50 patients admitted to Imam Reza hospital in Mashhad who diagnosed with COVID-19 and have not responded to the standard three-drug protocol. Convenience sampling will be used. These patients will receive intravenous immunoglobulin (IVIg) before entering the intubation phase. Also patients under prophylaxis from thrombosis, in the case of the absence of contraindication, will receive heparin with prophylaxis dose. 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: age range within 18 to 25 years old; definitive diagnosis with COVID-19; having one of the factors of decrease in consciousness level, RR≥24، BP<90/60, Multi-lobe lung problem and hypoxemia; not responding to standard three-drug protocol of hydroxychloroquine/chloroquine + lupinavir/ritonavir + ribavirin. Non-inclusion criteria: comorbidities such as heart diseases.

Intervention groups

Patients with severe clinical symptoms for whom the standard three-drug protocol (hydroxychloroquine / chloroquine + lupinavir / ritonavir + ribavirin) was not responsive, receive intravenous immunoglobulin (IVIg) before entering the intubation phase. They will receive 0.4-0.5 gr/kg/day of IVIg in 3-5 doses (equal to about 30g daily in a case with 60 kg body weight).

Main outcome variables

Fever; respiration rate; pulse rate; SpO2; WBC; number of lymphocytes; LDH; Signal Recognition Particle (SRP); findings of CT scan

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200325046859N1**
Registration date: **2020-04-02, 1399/01/14**
Registration timing: **prospective**

Last update: **2020-04-23, 1399/02/04**
Update count: **1**

Registration date

2020-04-02, 1399/01/14

Registrant information

Name

Rozita khodashahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3858 3845

Email address

khodashahir@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date
2020-05-05, 1399/02/16

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of intravenous immunoglobulin (IVIg) in patients with severe COVID-19 (Before intubation phase) who have not responded to treatment with the standard three-drug protocol (hydroxychloroquine / chloroquine + lupinavir / ritonavir + ribavirin)

Public title
The efficacy of intravenous immunoglobulin (IVIg) in patients with severe COVID-19 who have not responded to standard three-drug protocol

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed consent for inclusion in the study Age range within 18 to 25 years old Definitive diagnosis with COVID-19 Having one of the factors of decrease in consciousness level, RR≥24، BP<90/60, Multi-lobe lung problem and hypoxemia Certainty about non responsiveness of standard three-drug protocol of hydroxychloroquine / chloroquine + lupinavir / ritonavir + ribavirin

Exclusion criteria:
Sensitivity to IVIg Having a comorbidities such as heart diseases that IVIg cannot be used

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2020-03-30, 1399/01/11

Ethics committee reference number
IR.MUMS.REC.1399.013

Health conditions studied

1

Description of health condition studied
COVID-19 disease

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
fever

Timepoint
before and after treatment

Method of measurement
Thermometer

2

Description
respiration rate

Timepoint
before and after treatment

Method of measurement
counting the number of breaths patients take per minute

3

Description
findings of chest CT scan

Timepoint
before and after treatment

Method of measurement
CT scan machine

4

Description
pulse
Timepoint
before, during and after treatment
Method of measurement
patient monitoring device

5

Description
SpO2
Timepoint
before, during and after treatment
Method of measurement
patient monitoring device

6

Description
WBC
Timepoint
before and after treatment
Method of measurement
biochemical tests

7

Description
number of lymphocytes
Timepoint
before and after treatment
Method of measurement
biochemical tests

8

Description
Lactate dehydrogenase
Timepoint
before and after treatment
Method of measurement
biochemical tests

9

Description
C-Reactive Protein (CRP)
Timepoint
before and after treatment
Method of measurement
biochemical tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with severe clinical symptoms for whom the standard three-drug protocol (hydroxychloroquine / chloroquine + lupinavir / ritonavir + ribavirin) was not responsive receive intravenous immunoglobulin (IVIg) before entering the intubation phase. They will receive 0.4-0.5/g/kg/day of IVIg in 3-5 doses with each dose being equal to about 30g with a weight of 60 kg. Also patients under prophylaxis from thrombosis, in the case of the absence of contraindication, will receive heparin with prophylaxis dose.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Rozita Khodashahi
Street address
Imam Reza Hospital, next to Imam Reza square, Ibne Sina street
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Email
khodashahir@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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91778-99191
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ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Rozita Khodashahi

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Infectious diseases

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Imam Reza Hospital, next to Imam Reza square, Ibne Sina street

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is 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
Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

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