

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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, $RR \geq 24$, $BP < 90/60$, 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 \geq 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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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

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

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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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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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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