

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effectiveness of IVIg therapy on blood (WBC, lymphocyte count), renal (Cr, urea) and liver parameters (AST, ALT) in COVID-19 patients before and after IVIg therapy.

Protocol summary

Study aim

Determining the effectiveness of IVIG therapy on hematologic laboratory parameters (WBC, lymphocyte count), renal (Cr, Urea) and liver (AST, ALT) in patients with COVID-19 before and after IVIg treatment

Design

In this study, we first reviewed the records of patients admitted with COVID-19 and selected 98 cases that were treated with IVIG with 98 patients who were admitted for the same reason and with almost the same age and sex conditions without receiving IVIG. be. Then, the information and results of laboratory parameters will be extracted from the laboratory system and patients' clinical and demographic information in coordination with medical records from their files.

Settings and conduct

In this study, in order to recognize the effect of IVIg, the results of various parameters such as WBC count, Lymphocyte count, platelets, sodium, potassium, urea, creatinine, AST, ALT, interleukin 6, CRP, ESR, LDH, d-Dimer before and after treatment With IVIg, it is extracted from the HIS system of Milad and Al-Zahra hospitals in Isfahan and their changes are compared

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having laboratory and clinical results of COVID-19 2. Positive PCR test for COVID-19 3. Do not have other allergic diseases and cancer Exclusion criteria: 1. Death of the patient 2. Taking any immunosuppressive drugs during treatment

Intervention groups

Patients with severe or severity of COVID-19 disease who have not responded to other treatments and are indicated for IVIg treatment according to their physician will be included in the study. And patients in the control group will be selected in terms of sex and age almost similar to the study group

Main outcome variables

Serum IL-6 levels; Serum BUN level; Serum Cr level; Fever; Oxygen saturation; Lymphocyte count; Platelet count; K; Na; AST; ALT; LDH; D-dimer; ESR; CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220213054013N1**

Registration date: **2022-03-09, 1400/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-09, 1400/12/18**

Update count: **0**

Registration date

2022-03-09, 1400/12/18

Registrant information

Name

Behrooz Ghezelbash

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-04-09, 1401/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of IVIg therapy on blood (WBC, lymphocyte count), renal (Cr, urea) and liver parameters (AST, ALT) in COVID-19 patients before and after IVIg therapy.

Public title

Evaluation of the effectiveness of IVIg therapy on Covid 19 patients.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having laboratory and clinical results of COVID-19
Positive PCR test for COVID-19 Do not have other allergic diseases and cancer

Exclusion criteria:

Taking any immunosuppressive drugs during treatment

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **196**

More than 1 sample in each individual

Number of samples in each individual: **2**

Blood samples before IVIg and on the fourth day after receiving it

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 Isfahan University of Medical Sciences

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Hezar Jerib St., Isfahan University of Medical Sciences and Health Services

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Postal code

81746-73461

Approval date

2022-02-02, 1400/11/13

Ethics committee reference number

IR.ARI.MUI.REC.1400.058

Health conditions studied**1****Description of health condition studied**

Coronavirus (Covid-19)

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Serum IL-6 levels

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Measurement of the level of IL-6 before and 4 days after the intervention in comparison with the control group with laboratory equipment

2**Description**

Serum BUN level

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Measurement of the level of BUN before and 4 days after the intervention in comparison with the control group with laboratory

3**Description**

Serum Cr level

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Measurement of the level of Cr before and 4 days after the intervention in comparison with the control group with laboratory

4

Description

Fever

Timepoint

The day before the intervention until the fourth after the intervention

Method of measurement

Measurement of the patient's body temperature before and after treatment up to the fourth day after the intervention and comparison of the two groups

5

Description

Oxygen saturation rate

Timepoint

The day before the intervention until the fourth day after the intervention

Method of measurement

Measurement of oxygen saturation in arterial blood of the patient before and after treatment up to the fourth day after the intervention and comparison of the two groups

6

Description

Lymphocyte count

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Counting of patients' blood lymphocytes (number per microliter) before and 4 days after the intervention in comparison with the control group with laboratory equipment

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Description

Platelet count

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Counting of patients' blood platelets (number per microliter) before and 4 days after the intervention compared with the control group using cell counter.

8

Description

Serum sodium level (Na)

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Measurement of sodium in the patient's blood in terms of milliequivalents per liter, before and after treatment until the fourth day after the intervention and comparison of the two groups using a flame photometer

9

Description

potassium (K)

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Measurement of potassium in the patient's blood in milliequivalents per liter, before and after treatment until the fourth day after the intervention and comparison of the two groups using a flame photometer

10

Description

AST

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Assessment of AST enzyme level before intervention and 4 days after comparison with control group using autoanalyzer

11

Description

ALT

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Assessment of ALT enzyme level before intervention and 4 days after comparison with control group using autoanalyzer

12

Description

LDH

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Assessment of LDH enzyme level before intervention and 4 days after comparison with control group using autoanalyzer

13

Description

D-dimer

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Measurement of D-dimer before and 4 days in comparison with the control group using laboratory equipment

14

Description

ESR

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Measurement of ESR before and 4 days compared to the control group using Westergreen method

15

Description

CRP

Timepoint

The day before the intervention and the fourth day after the intervention

Method of measurement

Measurement of CRP in patients' serum before and 4 days after the intervention in comparison with the control group using an autoanalyzer

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group": In this study, patients with severe type or severity of COVID-19 disease, in addition to other treatments and according to the doctor, had a dose of IVIg treatment, will be included in the study. To eliminate confounders, the control group is used for adaptation and the patients in the control group will be selected almost similar to the study group in terms of sex and age. The results of hematological, hepatic and renal parameters before IVIg injection will be compared with the results of the fourth day after IVIG and will be analyzed.

Category

Treatment - Drugs

2

Description

"Control group": In this study, the control group of patients with severe or severity of COVID-19 disease who receive other therapies of the intervention group except IVIg will be included in the study. This work is used to eliminate confounding factors and for fitting, and patients in the control group will be selected almost similar to the study group in terms of sex and age. The results of hematological, hepatic and renal parameters before IVIg injection will be compared with the results of the fourth day after IVIG and will be analyzed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital Isfahan

Full name of responsible person

Behrooz Ghezelbash

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2

Recruitment center

Name of recruitment center

Milad Hospital of Isfahan

Full name of responsible person

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Shahrak-e Valieasr (Keshavarz Blvd), Isfahan, Isfahan, Iran,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Behrooz Ghezelbash

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Hematology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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Position

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Latest degree

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results of tests and clinical findings of patients will be presented in the article after the publication of the article.

When the data will become available and for how

long

6 months later

To whom data/document is available

Fields of the Department of Medical Sciences and scientists in this field

Under which criteria data/document could be used

To use or not to use this type of treatment according to the results

From where data/document is obtainable

Use the extracted article or request it from Behrooz

Ghezelbash via email.

behroozghezelbash@med.mui.ac.ir

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

By prior arrangement and sending email

Comments