Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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
Street address
Hezar Jerib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
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

7

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

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Sponsors / Funding sources

1

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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
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
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Full name of responsible person
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Position
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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