

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Dec 2023

Intravenous immunoglobulin (IVIG) effect on improvement of severe pulmonary damage in COVID 19 disease

Protocol summary

Study aim

Intravenous immunoglobulin (IVIG) effect on improvement of severe pulmonary damage in COVID 19 disease according to improvement in o2 saturation, mortality, hospital and ICU stay, improvement of fever and lung involvement in lung CT scan

Design

In this pilot study 40 patients with definite COVID 19 with poor response to first line drugs including at least one antiviral and chloroquine drugs, which have O2 saturation less than 90% and more than 30 percent involvement in lung CT scan randomly will assign into two groups, first group will receive intravenous immunoglobulin with a dose of 20 gram per day for at least 3 days, control group will take placebo, patients will be evaluated for improvement in o2 saturation (increasing above 90%) hospital death, improvement of fever, and ICU stay. Randomization will be performed by means of a computer-generated randomization schedule, and only the pharmacist of center will have knowledge about drug or placebo and , neither the patients nor the physicians nor whom responsible for data analysis will be aware of the types of treatment allocated. We will use 5 gr IVIG vials, so 4 vials will be used for each patient every 24 hours for at least 3 days. control group will receive placebo.

Settings and conduct

Ayatollah Talegani hospital

Participants/Inclusion and exclusion criteria

more tahn 30% involvement of lungs, age>18, no response to first line drugs

Intervention groups

definite COVID 19

Main outcome variables

improvement in o2 saturation , dyspnea, shortening of hospital stay and decreased mortality

General information

Reason for update

Acronym

IVIG(intravenous immunoglobulin)

IRCT registration information

IRCT registration number: **IRCT20200501047259N1**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Naser Gharebaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3344 4593

Email address

gharabaghi.n@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2020-06-09, 1399/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intravenous immunoglobulin (IVIG) effect on improvement of severe pulmonary damage in COVID 19 disease

Public title

IVIG and COVID19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

established COVID 19 in PCR test age more than 18 no response to at least one antiviral and chloroquine drugs more than 30% involvement in chest computed tomography

Exclusion criteria:

pregnant women coagulopathies previous hypersensitivity to IVIG left ventricular ejection fraction less than 35% previous lung fibrosis or lung surgery LUNG SARCOIDOSIS OR TUBERCULOSIS

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

computer- generated random number table

Blinding (investigator's opinion)

Triple blinded

Blinding description

randomization of patients will be done by computer-generated random number table and the pharmacist of center only will have knowledge of the randomization code. neither the patients nor the physicians nor those responsible for data analysis were aware of the types of treatment allocated. vials of IVIG and placebo will be in the same shape only code on them different

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Kashani street

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2020-04-08, 1399/01/20

Ethics committee reference number

IR.UMSU.REC.1399.025

Health conditions studied

1

Description of health condition studied

COVID19

ICD-10 code

COVID19

ICD-10 code description

COVID19

Primary outcomes

1

Description

increasing of patient's O2 saturation above 90%, improvement of lung involvement in lung CT scan

Timepoint

before discharge

Method of measurement

percentile

Secondary outcomes

empty

Intervention groups

1

Description

Immune Globulin intravenous (human) flebogamma 5% DIF GRIFOLS will be used, each vial has 5 gram IVIG and patient will receive 4 vial every day for 3 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Talegani hospital

Full name of responsible person

Naser Gharebaghi

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kashani street

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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urmia

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Naser Gharebaghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

SPSS file

When the data will become available and for how long

6 months after publication

To whom data/document is available

researchers of valid institutes

Under which criteria data/document could be used

for further evaluation and meta analysis

From where data/document is obtainable

Urmia University of medical sciences

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

Requests should be sent by email to Urmia University of Medical Sciences

Comments