Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

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

Protocol summary

Study aim

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

Public title
IVIG and COVID19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
stablished 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
Street address
kashani street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences
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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
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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
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 furthur 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