

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Oct 2020

### 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

**Street address**

kashani street

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Phone**

+98 44 3344 4593

**Email**

hajizadh.reza@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Naser Gharebaghi

**Street address**

Kashani street

**City**

urmia

**Province**

West Azarbaijan

**Postal code**

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**Phone**

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**Email**

hajizadh.reza@gmail.com

**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

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Reza Hajizadeh

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

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kashani street talegani hospital

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Reza Hajizadeh

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

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**Email**

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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**