# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 Oct 2020

## 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
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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
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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**