

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### To evaluate the effectiveness of intravenous immunoglobulin (IVIG) for the treatment of COVID-19-induced cytokine storm

#### Protocol summary

##### Study aim

The effectiveness of Intravenous immunoglobulin (IVIG) for the treatment of Coronavirus induced cytokine storm will be studied.

##### Design

A clinical trial with a control group, with parallel groups, simple-randomly assigned to intervention and control groups, Phase 3, 100 patient

##### Settings and conduct

This study will be performed in Imam Reza Hospital, Tabriz, Iran. 100 patients will be divided into two groups (50 in each group) by simple randomization. Patients in the control group will be prescribed a standard regimen for COVID-19. The intervention group will be prescribed by intravenous immunoglobulin 100-200 mg oral two times daily for two days and a standard regimen for COVID-19. CT scan of lungs, biochemical tests, hospitalization period, need to intubation and mortality rate will be assessed in both groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with moderate to severe cytokine storm and respiratory symptoms (ARDS); Patients with a respiratory rate of more than 30; PaO<sub>2</sub>/FiO<sub>2</sub> less than 300 mm Hg; Age 18-65 year. Exclusion criteria: sensitivity to IVIG, IgA deficiency syndrome; pregnant or lactating women; severe respiratory failure; immediate need for intubation

##### Intervention groups

Intervention group: will receive a standard regimen for COVID-19 plus intravenous immunoglobulin (IVIG). Control group: will receive a standard regimen for COVID-19.

##### Main outcome variables

The change of pneumonia severity on CT scanning; decrease hospitalization period; decrease ARDS symptoms; decrease mortality; decrease hospitalization period

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200317046797N3**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **prospective**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

##### Registration date

2020-04-11, 1399/01/23

##### Registrant information

##### Name

Sepideh Zununi Vahed

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3336 9331

##### Email address

sepide.zununi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-20, 1399/02/01

##### Expected recruitment end date

2020-07-22, 1399/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

To evaluate the effectiveness of intravenous immunoglobulin (IVIG) for the treatment of COVID-19-induced cytokine storm

## Public title

Intravenous immunoglobulin (IVIG) in the treatment of COVID-19-induced cytokine storm

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Respiratory rate more than 30 PaO<sub>2</sub>/FiO<sub>2</sub> less than 300 mm Hg Positive PCR for COVID -19 Age 18-65 year

### Exclusion criteria:

Sensitivity to IVIG Pregnancy IgA deficiency syndrome

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Simple randomization will be generated with a computer from 1 to 100. The computer will divide the digits between the two groups. According to the sequences of admission, they will go to the control or the IVIG group regarding the computerized random list.

## 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 Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Golgasht Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

## Approval date

2020-03-30, 1399/01/11

## Ethics committee reference number

IR.TBZMED.REC.1399.003

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19

#### ICD-10 code

U07.1

#### ICD-10 code description

U07.1: COVID-19, virus identified

### 2

#### Description of health condition studied

Coronavirus (COVID-19)-induced pneumonia

#### ICD-10 code

J12.81

#### ICD-10 code description

Pneumonia due to SARS-associated coronavirus

## Primary outcomes

### 1

#### Description

Improving the general condition of the patient

#### Timepoint

Before and after intervention

#### Method of measurement

Lung CT scan; No need to receive any intensive respiratory care in the patient

### 2

#### Description

Mortality rate

#### Timepoint

At baseline and discharge time or patient death

#### Method of measurement

Observation

### 3

#### Description

Need for intubation

#### Timepoint

Period of hospitalization

#### Method of measurement

Observation or reading of hospitalized documents

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: 50 patients with Coronavirus (COVID-19)-induced moderate or severe pneumonia in addition to the standard regimen of covid-19, will receive IVIG for 2 days (100-200 mg two-wise a day). Privigen, Behring company, Switzerland

### Category

Treatment - Drugs

## 2

### Description

Control group: will receive a standard regimen of covid-19 based on national protocol including Hydroxychloroquine, Ribavirin and Kaletra).

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imamreza Hospita of Tabriz

#### Full name of responsible person

Dr Khalil Ansarin

#### Street address

Imamreza Hospital, Daneshgah Street

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614756

#### Phone

+98 41 3334 7054

#### Email

imamreza@tbzmed.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Dr Mohammad Samiei

#### Street address

3th floor of Tabriz University of Medical Sciences  
Central Building, Golgasht Street, Tabriz

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

#### Phone

+98 41 3335 7310

### Email

Samiei.moh@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Mohammadreza Ardalan

#### Position

Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

Tabriz University of Medical Sciences

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

#### Phone

+98 41 3336 9331

#### Email

ardalan34@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Mohammadreza Ardalan

#### Position

Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

Tabriz University of Medical Sciences

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3336 9331

**Email**

ardalan34@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sepideh Zununi Vahed

**Position**

Assistant Prof.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biotechnology

**Street address**

Tabriz University of Medical Sciences

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3336 9331

**Email**

sepide.zununi@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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