

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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; PaO₂/FiO₂ 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 PaO₂/FiO₂ 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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Other areas of specialty/work

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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