Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Immamreza Hospita of Tabriz
Full name of responsible person
Dr Khalil Ansarin
Street address
Imamreza Hospital, Daneshgah Street
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5166614756
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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3th floor of Tabriz University of Medical Sciences Central Building, Golgasht Street, Tabriz
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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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Person responsible for updating data

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Sepideh Zununi Vahed

Position

Assistant Prof.

Latest degree

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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