

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of Fingolimod for treatment of COVID-19-induced cytokine storm

Protocol summary

Study aim

Effect of Fingolimod on clinical improvement and outcome of patients with Coronavirus-induced pneumonia will be studied

Design

A clinical trial with a control group, with parallel groups, simple-randomly assigned to intervention and control groups, Phase 3, 40 patients

Settings and conduct

This study will be performed in Imam Reza Hospital, Tabriz, Iran. 40 patients will be divided into two groups (20 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 fingolimod 50 mg oral one time daily for three days and standard regimen for COVID-19.-19. The routine lab data blood cell count, CT scan of lungs, hospitalization period, need to intubation and mortality rate will be assessed in both gr

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with moderate to severe 2019-nCoV-infected patients; 18 Years to 80 Years; both genders, positive PCR. Non-inclusion criteria: Patients with elevated liver enzymes (3 times); active pulmonary tuberculosis; definite bacterial and fungal infections; pregnant or lactating women; an active thrombotic event; severe respiratory failure; severe kidney failure (GFR<30 ml/min); immediate need for intubation

Intervention groups

Control group: will receive a standard regimen for COVID-19. Intervention group: will receive a standard regimen for COVID-19 plus fingolimod

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

FingoCov

IRCT registration information

IRCT registration number: **IRCT20200317046797N2**

Registration date: **2020-04-03, 1399/01/15**

Registration timing: **prospective**

Last update: **2020-04-03, 1399/01/15**

Update count: **0**

Registration date

2020-04-03, 1399/01/15

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

2020-04-08, 1399/01/20

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Fingolimod for treatment of COVID-19-induced cytokine storm

Public title

Effect of Fingolimod for treatment of COVID-19-induced cytokine storm

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Moderate to severe 2019-nCoV-infected 18 Years to 80 Years Patients or authorized family members volunteered to participate in this study and signed informed consent Both genders

Exclusion criteria:

Patient with elevated liver enzymes (3 times) Patients who are participating in other drug clinical trials Patients with active pulmonary tuberculosis Patients with definite bacterial and fungal infections Pregnant or lactating women Patient with active thrombotic event

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be generated with a computer from 1 to 40. The computer will divide the digits between the two groups. According to the sequences of admission, they will go to the control or the fingolimod 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

2020-03-24, 1399/01/05

Ethics committee reference number

IR.TBZMED.REC.1399.001

Health conditions studied

1

Description of health condition studied

Coronavirus (COVID-19)-induced pneumonia

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

2

Description of health condition studied

Coronavirus (COVID-19)-induced pneumonia

ICD-10 code

J12.8

ICD-10 code description

Primary outcomes

1

Description

Improvement of the symptoms of lung, pulmonary infiltrates

Timepoint

At baseline (before intervention) and 2 day after drug administration

Method of measurement

Lung CT scan

2

Description

Decreased hospitalization period

Timepoint

At baseline and discharge time

Method of measurement

counting the hospitalization days

3

Description

Mortality rate

Timepoint

At baseline and discharge time

Method of measurement

observation

4

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: Twenty patients with Coronavirus (COVID-19)-induced pneumonia addition to standard regimen of covid-19, will receive Fingolimod for 1 day (50 mg one time).

Category

Treatment - Drugs

2

Description

Control group: standard regimen of covid-19 patients

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, Golgasht street

City

tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3335 2073

Email

dr.ansarin@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Samiei

Street address

Third floor of Tabriz University of Medical Sciences
Central Building, Golgasht Street, Tabriz

City

Tehran

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

Dr Khalil Ansarin

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Imamreza Hospital-Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3335 2898

Email

dr.ansarin@gmail.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
Golgasht street
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

golgasht srteet, 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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable