

# 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

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##### 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

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#### Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**  
Tabriz University of Medical Sciences  
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Mohammadreza Ardalan  
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Professor  
**Latest degree**  
Subspecialist  
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Internal Medicine  
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## **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

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### **Province**

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### **Phone**

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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**

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