Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 41 3336 9331

Email address
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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
Immamreza Hospita of Tabriz
Full name of responsible person
Dr Khalil Ansarin
Street address
Imamreza Hospital, Golgasht 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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Third 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
Dr Khalil Ansarin
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific

inquiries

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Position
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Person responsible for updating data

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Position
Assistant Prof.

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Other areas of specialty/work
Medical Biotechnology

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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