Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

A clinical trial comparing the effect of Fenofibrate on the prognosis in hospitalized patients with COVID-19

Protocol summary

Study aim
Evaluation of Fenofibrate effect on the prognosis in hospitalized patients with COVID-19

Design
A phase 3 double-blinded randomized clinical trial consisted of a placebo group with a total of 69 admitted patients following COVID-19 using the simple randomization method.

Settings and conduct
In this double-blind trial, patient recruitment and treatment were performed in Besat hospital in Tehran. All patients received standard of care according to the last version (8th edition) of the national management protocol for COVID-19 patients. Using the simple randomization method, numbers from 1 to 70 were randomly grouped and patients were consecutively allocated to one of the two study groups based on the table starting from 1. In the intervention group, the patient was given 200 milligrams of Fenofibrate capsule per day orally (each capsule contains 100 milligrams given twice a day) beside usual care. In the control group, the patient received a placebo with a similar appearance to the intervention drug along with the usual care. For this purpose, we used the following website, https://www.graphpad.com/quickcalcs/randomize1 The total number of groups (2 groups) and 35 patients in each group were entered and numbers 1, 2, 3... to 70 were assigned to groups A (intervention) and B (control).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged more than 18 years who need hospitalization with a confirmed diagnosis of COVID-19 by RT-PCR. Exclusion criteria: pregnancy, breastfeeding, hypersensitivity or history of fibrate agents, history of active liver or renal diseases, and hypothyroidism.

Intervention groups
There were two groups in this study including the intervention group receiving Fenofibrate orally and standard of care, and the control group receiving placebo and standard of care.

Main outcome variables
Mortality and need for intensive care unit (ICU)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220612055149N1**
Registration date: **2022-07-24, 1401/05/02**
Registration timing: **retrospective**

Last update: **2022-07-24, 1401/05/02**
Update count: **0**

Registration date
2022-07-24, 1401/05/02

Registrant information
Name
Farbod Hatami
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-05, 1400/02/15

Expected recruitment end date
2021-11-05, 1400/08/14

Actual recruitment start date
2021-05-05, 1400/02/15

Actual recruitment end date

2021-11-05, 1400/08/14

Trial completion date

2022-02-12, 1400/11/23

Scientific title

A clinical trial comparing the effect of Fenofibrate on the prognosis in hospitalized patients with COVID-19

Public title

Evaluation of efficacy and safety of Fenofibrate in COVID-19 patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 18 years Confirmed diagnosis of COVID-19 with RT-PCR Hospitalization Symptom onset lower than 10 days

Exclusion criteria:

Pregnancy, breastfeeding Known hypersensitivity to fibrate agents History of Fenofibrate treatment Previous treatment with warfarin, ciclosporin, tacrolimus, and atorvastatin more than 40 milligrams (mg) daily History of liver diseases, and hypothyroidism

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Actual sample size reached: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method was applied for the current study to determine the study group for each patient (intervention or placebo). Therefore, numbers from 1 to 70 were grouped as intervention or placebo using random allocation. After the patients were enrolled, they were allocated to one of the two study groups using the table of numbers starting from 1.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, the physician, and the outcome assessor were blind as to which study group the patient was allocated. Placebo had similar appearance characteristics including odor and color as the study medication in the intervention group. Placebo and the drug were grouped as A and B as neither the distributor nor the patient knew the labeling information.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of AJA University of Medical Sciences

Street address

West Fatemi St., Shahid Etemadzadeh St.

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-02-17, 1399/11/29

Ethics committee reference number

IR.AJAUMS.REC.1399.240

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Mortality

Timepoint

From admission to 3 months after discharge

Method of measurement

Electronic records and contacting patient after discharge

2

Description

ICU admission

Timepoint

From hospitalization to discharge

Method of measurement

Patient status by electronic records

Secondary outcomes

1

Description
Hospitalization days
Timepoint
At discharge
Method of measurement
Patient electronic records

2

Description
ICU stay
Timepoint
At dischagre
Method of measurement
Patient electronic records

3

Description
Mechanical ventilaton
Timepoint
At discharge
Method of measurement
Need for mechanical ventilation by reviewing electronic records.

Intervention groups

1

Description
Intervention group: Patients admitted following COVID-19 receive 200 milligrams of Fenofibrate capsule by Sobhan Darou including one 100 milligram capsule every 12 hours orally during hospitalization days for a maximum period of 14 days. In both study groups, patients receive further similar treatments according to the national guideline for the standard of care in COVID-19.
Category
Treatment - Drugs

2

Description
Control group: Patients receive an oral placebo by Sobhan Darou every 12 hours. Also, patients receive standard of care treatments as recommended by the national COVID-19 committee and in line with national guidelines similar to those in the intervention group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital
Full name of responsible person
Farbod Hatami
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh 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
Birjand University of Medical Sciences
Full name of responsible person
Farbod Hatami
Position
Consultant

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data regarding clinical outcomes and those variables of clinical importance will be potentially published through a scientific article after making personal data of our patients undetectable.
When the data will become available and for how long
Access date is based on an agreement with the publisher of the scientific article probably after print for a period of 2 years
To whom data/document is available
Faculty of medical universities
Under which criteria data/document could be used
Research purposes
From where data/document is obtainable
Email of the corresponding author: Syrous.faraji@yahoo.com
What processes are involved for a request to access data/document
An email to the corresponding author
Comments