

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 fibrates 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3162 6459

Email address

f.hatami@bums.ac.ir

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 discharge

Method of measurement

Patient electronic records

3

Description

Mechanical ventilator

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

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba Yousefi Zoshk

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Email

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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

Medical doctor

Other areas of specialty/work

General Practitioner

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Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Sirus Faraji

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data**Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Farbod Hatami

Position

Consultant

Latest degree**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