

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Comparative bioequivalence study of two different Fenofibrate 200mg formulations (Aviccena Pharmaceutical Company & reference) in 24 Iranian volunteers

Protocol summary

Study aim

Evaluation of bioequivalence of a 200 mg Fenofibrate capsule manufactured by Aviccena Pharmaceutical Company with its reference sample

Design

Bioequivalency study of Fenofibrate 200 mg capsule manufactured by Aviccena Pharmaceutical Company and reference product in 24 healthy volunteers. This study was cross-over, random, and double-blind. Excel rand function was used for randomization

Settings and conduct

This study is carried out in the central laboratory of the Hamadan School of Pharmacy. The 24 volunteers are randomly divided into two groups and are divided into two stages of the study. This study is double-blind and the recipient and analyzer will not be in the process of consuming the product. Blood samples will be collected from each volunteer at specified times for 24 hours. The method used to measure the amount of drug in the samples of volunteers will be performed using high-performance liquid chromatography and an ultraviolet detector.

Participants/Inclusion and exclusion criteria

Ages 18 to 45 years, Actual weight (TBW) in the range of 20% IBW, Non-smoker

Intervention groups

Fenofibrate Capsule formulated at Aviccena Pharmaceutical company 2. Fenofibrate Capsule formulated at Mylan company

Main outcome variables

Fenofibrate plasma concentration; Area under the curve; Half-life time; Time to reach maximum plasma concentration; Maximum concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111107008022N10**

Registration date: **2023-01-30, 1401/11/10**

Registration timing: **prospective**

Last update: **2023-01-30, 1401/11/10**

Update count: **0**

Registration date

2023-01-30, 1401/11/10

Registrant information

Name

Katayoun Derakhshandeh

Name of organization / entity

Hamadan University of Medical Sciences, Pharmacy school

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1590

Email address

kderakhshandeh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-02-23, 1401/12/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of two different Fenofibrate 200mg formulations (Aviccena Pharmaceutical Company & reference) in 24 Iranian volunteers

Public title

Bioequivalence study of two different Fenofibrate formulations

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy male and female volunteers Aged 18 to 45 years
Based on laboratory safety tests, no history of diseases affecting drug pharmacokinetic processes lack of any chronic or acute medication at least 1 week before the start of the study Actual weight (TBW) in the range of 20% IBW

Exclusion criteria:

Subject showed clinically relevant deviations from normal in physical examination Subject had undergone surgery of the gastrointestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last three months before the first treatment Subject had a history of alcohol abuse or smokes more than 10 cigarettes per day Use any medication within 14 days before the first treatment

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 24 volunteers were randomly divided into two groups of 12 test (A) and reference (B) drug recipients by Excel software, then in the second phase, groups A and B will be cross-referenced to the test and drug recipients.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this project, the volunteers, person responsible for blood sampling and analyzer are kept blind. To blind these people, all the information collected is coded to the researcher, and after the analysis is completed, codes will be opened.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committees of Hamadan University of Medical Sciences

Street address

School of Pharmacy, Hamadan University of Medical Sciences, Beside Mardom amusement Park, Shahid Fahmideh Blvd, Hamadan , Iran

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.UMSHA.REC.1401.943

Health conditions studied

1

Description of health condition studied

Health and normal volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

Blood samples were collected at 0, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10, 12, 24, 48, 72, 96 hour following drug administration

Method of measurement

Using High Performance Liquid Chromatography instrument

Secondary outcomes

1

Description

Pharmacokinetic parameters

Timepoint

0; 0.5; 1.0; 2.0; 3.0; 4.0; 4.5; 5.0; 5.5; 6.0; 6.5; 7.0; 8.0; 9.0; 10.0; 12.0; 16.0; 20.0; 24.0; 48.0; 72.0; 96.0 hour post-dose

Method of measurement

Drug analysis in plasma using a chromatographic

apparatus and calculating pharmacokinetic parameters using pharmacokinetic models

Intervention groups

1

Description

Intervention group: Single dose of Fenofibrate 200 mg tablet manufactured by Mylan Pharmaceutical company in 24 healthy volunteers

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Pharmacy, Hamadan University of Medical Sciences

Full name of responsible person

Katayoun Derakhshandeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Aviccena Pharmaceutical Company

Full name of responsible person

Siamack Mirtorabi

Street address

Yusefabad, Jahanara Ave, 23rd St, No. 8, Tehran, Iran

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1438933741

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Email

qateh@avicenna.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Aviccena Pharmaceutical Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr.Katayoun Derakhshandeh

Position

Professor of Pharmaceutics

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Name of organization / entity

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

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The pharmacokinetic data obtained from the study are for each volunteer in both the test and reference groups.

When the data will become available and for how long

6 months after the end of the study

To whom data/document is available

All researchers and clinical specialists

Under which criteria data/document could be used

There is no denial of access to data

From where data/document is obtainable

The results of the project are reported in the form of a published paper. Article will be available after it is published. If needs quicker access to the results, can reach us at "k.derakhshandeh@umsha.ac.ir"

What processes are involved for a request to access data/document

There will be no problem accessing results when publishing results in online articles. The wait time to access the results will be 3 months after the project is completed. If needs quicker access to the results, can reach us at "k.derakhshandeh@umsha.ac.ir".

Comments