Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Bioequivalence of Fenofibrate ۲۰۰ mg in Healthy Volunteers

Protocol summary

Study aim

The aim of this report is comparison of pharmacokinetic parameters of Fenofibrate 200 mg manufactured by Aani Darman versus Abbot in 24 healthy volunteers in vivo and in vitro. Statistical data analysis and finding if the Aani Darman product is proper or not.

Design

Subjects were simple randomized to either of the two treatment arms (test or reference) separated by a washout period of 7 days. Each subject is randomly allocated to either an AB sequence or a BA sequence.

Settings and conduct

In a crossover study, each subject receives both drugs (T and R); one in one subgroup of the study and the other in a second subgroup. Essentially, subjects in a crossover study are randomly assigned to one of two sequence groups. Subjects in sequence group 1 (i.e., AB) receive the test drug first, followed by the reference drug. Subjects in sequence group 2 (i.e., BA) receive the reference drug first, followed by the test drug. there is a one week washout period between two subgroups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria:18 to 55 years old, Males and/or non-pregnant, non-lactating females, having a physical examination with no clinically significant finding and laboratory normal tests, do not take any chronic or acute medication for at least 1 week before the start of the study, no history of diseases affecting the pharmacokinetic processes of the drug. Exclusion criteria is described in the related part.

Intervention groups

Administration of fenofibrate test from Iranian manufacture and reference to healthy volunteers in two subgroup. The intervention is only one dose test or reference in first week and in the next week vise versa.

Main outcome variables

Area Under plasma Concentration(AUC) 0 to t, AUC 0 to infinite, Peak Concentration(Cmax), time to peak concentration(tmax)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221002056075N2**
Registration date: **2023-05-14, 1402/02/24**
Registration timing: **retrospective**

Last update: **2023-05-14, 1402/02/24**
Update count: **0**

Registration date

2023-05-14, 1402/02/24

Registrant information

Name
Sima Sadrai
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6695 9054
Email address
sadrai@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-02-09, 1401/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Bioequivalence of Fenofibrate ۲۰۰ mg in

Healthy Volunteers

Public title
Bioequivalence of Fenofibrate
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 55 years old, Males and/or non-pregnant, non-lactating females Body mass index (BMI) from 18.5 to 24.9 weight in kg/(height in meter), ability to communicate effectively with study personnel and willingness to follow the protocol requirements as evidenced by written informed consent having a physical examination with no clinically significant finding and laboratory normal tests, do not take any chronic or acute medication for at least 1 week before the start of the study no history of diseases affecting the pharmacokinetic processes of the drug
Exclusion criteria:
History of allergic responses to related drugs, or any of its formulation ingredients, have significant diseases (which might compromise the haemopoeitic, gastrointestinal, renal, hepatic, cardiovascular, respiratory, central nervous system, diabetes, psychosis or any other body system) or clinically significant abnormal findings during screening, history or presence of bronchial asthma history or evidence of drug dependence or of alcoholism or of moderate alcohol use, smokers who smoke 10 or more cigarettes per day or those who cannot refrain from smoking during the study period, history of difficulty with donating blood or difficulty in accessibility of veins, history of difficulty in swallowing, or of any gastrointestinal disease which could affect drug absorption. volunteers who have received a known investigational drug within five elimination half-life of the administered drug prior to the initial dose of study drug or who have participated in a clinical drug study or bioequivalence study within 90 days prior to the initial dose of study drug, whichever is greater, found positive in urine test for drugs of abuse done before check-in of period,
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects were simple randomized to either of the two treatment arms (test or reference) separated by a washout period of 7 days. The standard 2 × 2 crossover design is used to assess between two groups (test group A and control group B). Each subject is randomly allocated to either an AB sequence or a BA sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
The dosage forms are in boxes and the volunteers should not see what he or she takes. The coding of samples are only by code of subject and date.
Placebo
Not used
Assignment
Crossover
Other design features
no

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committees of The Institute of Pharmaceutical Sciences -Tehran University of Medical
Street address
The Institute of Pharmaceutical Sciences -Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۴۱۷۶۱۴۴۱۱
Approval date
2022-10-02, 1401/07/10
Ethics committee reference number
IR.TUMS.TIPS.REC.1401.056

Health conditions studied

1

Description of health condition studied
comparison of test and reference fenofibrate
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Comparison of plasma profile of test versus reference drug
Timepoint
From administration of drug since 48 hour
Method of measurement
with HPLC

Secondary outcomes

empty

Intervention groups

1

Description
The test (Aani darman company from Iran) fenofibrate 200 milligram capsules by a crossover design is given only once to the same volunteers. There we have a washout period (one week). Fenofibrate is used to treat primary hypercholesterolemia, mixed dyslipidemia, severe hypertriglyceridemia. Only the volunteers are by a simple randomizing divided to two groups. So we have a sequence effect. Group A, first test and next week reference. Group B, first reference and next week test.

Category
Other

2

Description
Control group: The reference (Abbot company, from USA, with brand name of Lipantyl) fenofibrate 200 milligram capsules by a crossover design is given only once to the same volunteers. There we have a washout period (one week). Only the volunteers are by a simple randomizing divided to two groups. So we have a sequence effect. Group A, first test and next week reference. Group B, first reference and next week test.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Healthy volunteers in the School of Pharmacy

Full name of responsible person
Sima Sadrai

Street address
Post Box 14155/6451, School of Pharmacy, Tehran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
۱۴۱۷۶۱۴۴۱۱

Phone
+98 21 6695 9054

Fax
+98 21 6646 1178

Email
sadrai@tums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Aani Ḏarman Pharmaceutical Company

Full name of responsible person
Dr Monir Saadat Ahmadi

Street address
No. 243,244, Golestan 9, Baharestan Indudustrial Township, Karaj

City
Alborz

Province
Alborz

Postal code
3197994602

Phone
+98 26 3762 1740

Fax
+98 26 3762 1750

Email
Ahmadi@aanidarman.com

Web page address
http://www.aanidarman.com

Grant name

Grant code / Reference number

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

Title of funding source
Aani Ḏarman 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
Tehran University of Medical Sciences

Full name of responsible person
Sima Sadrai

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
P.O.Box 14155/6451, School of Pharmacy, Tehran University of Medical Sciences, Tehran

City

Tehran

Province
Tehran

Postal code
۱۴۱۷۶۱۴۴۱۱

Phone
+98 21 6695 9054

Fax
+98 21 6646 1178

Email
sadrai@tums.ac.ir

Web page address
http://www.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Sima Sadrai

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
P.O.Box, 14155/6451, School of Pharmacy, Tehran University of Mediacl Sciences, Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۱۷۶۱۴۴

Phone
+98 21 6695 9054

Fax
+98 21 6646 1178

Email
sadrai@tums.ac.ir

Web page address
http://www.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Sima Sadrai

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
P.O.Box, 14155/6451, School of Pharmacy, Tehran University of Medical Sciences, Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۱۷۶۱۴۴

Phone
+98 21 6695 9054

Fax
+98 21 6646 1178

Email
sadrai@tums.ac.ir

Web page address
http://www.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It is order of a pharmaceutical company.

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
No - There is not 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