Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of Gemfibrozil 300-mg capsules manufactured by Daana Pharmaceutical Company versus Lopid® (Pfizer)

Protocol summary

Study aim

Demonstration of bioequivalence of gemfibrozil 300-mg capsule of Daana Pharmaceutical Company with Lopid® capsule manufactured by Pfizer after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of gemfibrozil 300-mg capsule by Daana Co. with Lopid® (Pfizer) in 24 healthy male volunteers in two groups under fasting condition.

Settings and conduct

Study place and the place for blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive each of test or reference gemfibrozil 300-mg capsule in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 7, 8, 12 and 24 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 20-60 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of TB, epilepsy, asthma, DM, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group 1: Gemfibrozil 300-mg capsule by Daana Co. is the test product. Intervention group 2: Lopid® (Pfizer) is the reference product. In each period, 12 of 24 subjects will be given single dose of this product. After the washout period, the volunteers are placed in the opposite group.

Main outcome variables

Peak plasma concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N28**
Registration date: **2022-04-09, 1401/01/20**
Registration timing: **prospective**

Last update: **2022-04-09, 1401/01/20**
Update count: **0**

Registration date

2022-04-09, 1401/01/20

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-05, 1401/06/14

Expected recruitment end date

2022-12-05, 1401/09/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of Gemfibrozil 300-mg capsules manufactured by Daana Pharmaceutical Company versus Lopid® (Pfizer)

Public title
Study of absorption and elimination rate of Gemfibrozil 300-mg capsule in comparison with gemfibrozil brand capsule (Lopid®).

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The weight limit of each volunteer should be between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the consent form.
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Gemfibrozil or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two weeks before dosing.

Age
From **20 years** old to **60 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
In each period, 12 of 24 subjects will be given single dose of this product (Domestic or brand). After the washout period, the volunteers are placed in the opposite group.

Randomization (investigator's opinion)
Randomized

Randomization description
To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of the both groups will change for the second period.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Science
Street address
Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766

Approval date
2022-03-01, 1400/12/10

Ethics committee reference number
IR.TBZMED.REC.1400.1189

Health conditions studied

1

Description of health condition studied
Bioequivalence study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
At 0 before dosing 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 7, 8, 12 and 24 hours after dosing

Method of measurement
High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)

Timepoint
At 0 before dosing 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 7, 8, 12 and 24 hours after dosing

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Gemfibrozil 300-mg capsule produced by Daana Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2.

Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Gemfibrozil 300-mg capsule (Lopid), produced by Pfizer Company (brand). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Drug Applied Research Center

Full name of responsible person
Dr Hamed Hamishehkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Daana pharmaceutical company

Full name of responsible person
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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
Daana 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
Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmaeutics

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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
There is no further information
Study Protocol
Undecided - It is not yet known if there will be 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
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
No - There is not a plan to make this available