Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

In vivo fasted-state bioequivalence study of Fexofenadine 6 mg/ml suspension manufactured by Omid Behbood Co. compared to innovator product

Protocol summary

Study aim

In vivo fasted-state bioequivalence study of Fexofenadine 6 mg/ml suspension

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy male volunteers will participate randomly in the study as two twelve-person study groups. Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation. Therefore, each volunteer will be his own "Control". To randomly assign participants in two groups, the lottery method will be used.

Settings and conduct

After oral administration of 10 mL Fexofenadine suspension, the blood samples will be collected in predetermined time intervals up to 24 hours. The samples will be stored in freezer -4 degrees centigrade until analysis. The concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences. This study will be conducted without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old) Exclusion criteria: Smoking, History of cardiovascular, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy.

Intervention groups

Intervention group will receive 10 mL oral dose of test product (Fexofenadine 6 mg/ml suspension of Omid Behbood Co.) and Control group will receive 10 mL of reference product (Fexofenadine 6 mg/ml suspension of SANOFI Co, Germany). Blood samples will be taken for 24 hours at the mentioned time points and the plasma will be stored in freezer until analysis. In both groups, breakfast and lunch will be served two and six hours after drug administration, respectively)

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051345N24**
Registration date: **2023-02-06, 1401/11/17**
Registration timing: **prospective**

Last update: **2023-02-06, 1401/11/17**
Update count: **0**

Registration date

2023-02-06, 1401/11/17

Registrant information

Name

Parvin Zakeri-Milani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8801

Email address

pzakeri@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-01, 1401/12/10

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo fasted-state bioequivalence study of Fexofenadine 6 mg/ml suspension manufactured by Omid Behbood Co. compared to innovator product

Public title

Investigating the in vivo bioequivalence of Fexofenadine suspension

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

General Health (in terms of Liver, Heart and Kidney)

Exclusion criteria:

Smoking History of cardiovascular disease, liver and kidney disease Pregnancy Alcohol and drug addiction History of drug allergy

Age

From **18 years** old to **59 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

To randomly assign participants 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. 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 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

Biomedical Research Committe, Tabriz University of Medical Sciences

Street address

3rd Floor; No.2 Central Building; Tabriz University of Medical Sciences; Daneshgah street

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2023-01-23, 1401/11/03

Ethics committee reference number

IR.TBZMED.REC.1401.978

Health conditions studied

1

Description of health condition studied

In the present study, the products will be administered to healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration of drug

Timepoint

0.5-24 hours in predetermined time intervals after drug administration

Method of measurement

HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group will receive 10 mL of test product (Fexofenadine suspension 6 mg/ml manufactured by Omid Behbood) in fasted state. Blood samples will be collected for 24 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.

Category

Treatment - Drugs

2

Description
Control group: Control group will receive 10 mL of reference product (Fexofenadine 6 mg/mL manufactured by SANOFI Co., Germany) in fasted state. Blood samples will be collected for 24 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Pharmacy, Tabriz University of Medical Sciences

Full name of responsible person
Parvin Zakeri-Milani

Street address
Faculty of Pharmacy, Tabriz University of Medical Sciences Golgasht st Attar Neishaboori st.

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+98 41 3334 8801

Email
pzakeri@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parviz Shahabi

Street address
No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.

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shahabip@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Omid Behbood Co.

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
Parvin Zakeri-Milani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori street, Golgasht street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parvin Zakeri-Milani

Position
Professor

Latest degree
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be 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
Not applicable

Data Dictionary
Not applicable