

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Investigating in vivo bioequivalence of Famotidine 40 mg/5 ml suspension manufactured by Omid Behboud Co.compared to innovator product

Protocol summary

Study aim

Investigating in vivo bioequivalence of Famotidine 40 mg/5 ml suspension

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy 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. 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 5 ml Famotidine suspension blood samples will be collected in predetermined time intervals up to 12 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. The concentration of drug in blood samples will be measured by liquid chromatography. The study will be performed in Tabriz University of Medical Sciences.

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 5 mL oral dose of test product (Famotidine suspension of Omid Behboud Co.) and Control group will receive 5 mL of reference product (Famotidine suspension of Lupin Co.). Blood samples will be taken for 12 hours at the mentioned time points after drug administration and the plasma will be stored in freezer until analysis.

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051345N44**

Registration date: **2024-01-22, 1402/11/02**

Registration timing: **prospective**

Last update: **2024-01-22, 1402/11/02**

Update count: **0**

Registration date

2024-01-22, 1402/11/02

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

2024-02-04, 1402/11/15

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating in vivo bioequivalence of Famotidine 40 mg/5 ml suspension manufactured by Omid Behboud Co.compared to innovator product		Tabriz
Public title		Province
Bioequivalence study of Famotidine Suspension		East Azarbaijan
Purpose		Postal code
Other		51664-14766
Inclusion/Exclusion criteria		Approval date
Inclusion criteria:		2024-01-14, 1402/10/24
General Health (in terms of Liver, Heart and Kidney), Age (18-59 years)		Ethics committee reference number
Exclusion criteria:		IR.TBZMED.REC.1402.782
Smoking, History of cardiovascular disease, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy		Health conditions studied
Age		<u>1</u>
From 18 years old to 59 years old		Description of health condition studied
Gender		In the present study, the products will be administered to healthy volunteers
Male		ICD-10 code
Phase		ICD-10 code description
Bioequivalence		Primary outcomes
Groups that have been masked		<u>1</u>
No information		Description
Sample size		Plasma concentration of drug
Target sample size: 24		Timepoint
Randomization (investigator's opinion)		0.5-12 hours in predetermined time intervals after drug administration
Randomized		Method of measurement
Randomization description		HPLC (High performance liquid chromatography)
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.		Secondary outcomes
Blinding (investigator's opinion)		empty
Not blinded		Intervention groups
Blinding description		<u>1</u>
Placebo		Description
Not used		Intervention group: Intervention group will receive 5 mL oral dose of test product (Famotidine suspension manufactured by Omid Behboud) in fasted state. Blood samples will be collected for 12 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
Assignment		Category
Crossover		Treatment - Drugs
Other design features		<u>2</u>
Secondary Ids		Description
empty		Control group: Control group will receive 5 mL oral dose of reference product (Famotidine suspension manufactured by Fizer) in fasted state. Blood samples will be collected for 12 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
Ethics committees		
<u>1</u>		
Ethics committee		
Name of ethics committee		
Biomedical Research Committe, Tabriz University of Medical Sciences		
Street address		
No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.		
City		

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, Attar Neishaboori st., Golgasht st.

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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, Daneshgah st. Tabriz University of Medical Science

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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 Behboud 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

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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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