Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence study of Famotidine 40 mg coated tablets of Medava Pharmaceutical Company with Famotidine 40 mg coated tablets of Telomed Pharmaceutical Company of England

Protocol summary

Study aim

Bioequivalence study of Famotidine 40 mg coated tablets of Medava Co. with Famotidine 40 mg coated tablets of Telomed Co.

Design

Single dose, crossover and randomized bioequivalence study of Famotidine 40 mg coated tablets of Medava Pharmaceutical Company with Famotidine 40 mg coated tablets of Telomed Pharmaceutical Company of England in 24 healthy volunteers in two groups.

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 volunteers will receive one of the 40 mg Famotidine tablets test or reference 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, 3.5, 4, 4.5, 5, 6, 8, 10, and 12 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18-30. Exclusion criteria: Subjects with Blood Pressure ≤ 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 tuberculosis, epilepsy, asthma, diabetes, psychosis or glaucoma and regular smoker.

Intervention groups

ntervention group 1: Famotidine tablet 40 mg by Modava Co. is the test product. Intervention group 2: Famotidine (Telomed) 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: **IRCT20130313012810N18**
Registration date: **2023-11-29, 1402/09/08**
Registration timing: **prospective**

Last update: **2023-11-29, 1402/09/08**
Update count: **0**

Registration date

2023-11-29, 1402/09/08

Registrant information

Name
Hamed Hamishehkar
Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date
2023-12-09, 1402/09/18
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Bioequivalence study of Famotidine 40 mg coated tablets of Medava Pharmaceutical Company with Famotidine 40 mg coated tablets of Telomed Pharmaceutical Company of England

Public title
Bioequivalence study of Famotidine 40 mg coated tablets of Medava Pharmaceutical Company with Famotidine 40 mg coated tablets of Telomed Pharmaceutical Company of England
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
The weight range of participating candidates should be between 60-100 kg Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw
Exclusion criteria:
History of allergic or adverse reaction to Azithromycin or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Smokers Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s)
Age
From **18 years** old to **60 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 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
Pharmacetical science Institude of Tehran university of medical science
Street address
Poursina Ave, Tehran University of Medical Science, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2023-07-18, 1402/04/27
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.055

Health conditions studied

1

Description of health condition studied
Bioequivalence study in healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of the drug
Timepoint
15 sampling time included pre-dose (time 0) and at the following hours post-dose: 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, and 12 h
Method of measurement

Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Famotidine tablet 40 mg produced by Modava 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
N/A

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Famotidine tablet 40 mg, produced by UK Tillomed 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
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

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Drug Applied Research Center, Tabriz University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Modava Pharmaceutical Company

Full name of responsible person
Asghar Heydari

Street address
5th floor, Shafayab Building, No. 275, Beheshti St.

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Tehran

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1514617714

Phone
+98 21 8817 5119

Email
info@modavaco.com

Grant name

Grant code / Reference number

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

Title of funding source
Modava 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
Medical Pharmacy

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Person responsible for scientific inquiries

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Position

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Latest degree

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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

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