Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Bioequivalence study of famotidine 40 mg tablets of Ramopharmin pharmaceutical company compared to Famotidine 40 mg of Ratiopharm GmbH in Germany on healthy volunteers.

Protocol summary

Study aim

Bioequivalence study of famotidine 40 mg tablets of Ramopharmin pharmaceutical company compared to Famotidine 40 mg of Ratiopharm GmbH in Germany on healthy volunteers.

Design

The present clinical trial includes the bioequivalence study of famotidine 40 mg tablets of Ramopharmin pharmaceutical company compared to the sample of famotidine 40 mg of Ratiopharm GmbH, Germany, after administration to 24 healthy human volunteers, it is in two intervention groups, cross-over, unblinded and non-randomized.

Settings and conduct

The study is carried out at Nik Azma Pars Alborz company located in Mahdasht Karaj. The blinded cross-over study includes two phases (oral consumption of one 40 mg famotidine tablet per study and 2 times in total) with a one-week washout period on 24 fasting healthy volunteers. Then the obtained blood samples are determined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy volunteers; Age between 18 and 55 years; non smoker; Exclusion criteria: candidates with blood pressure less than 90 on 60 mm Hg or higher than 140 on 90 mm Hg.

Intervention groups

The study includes two stages as intervention 1: including oral consumption of famotidine 40 mg tablets of Ramopharmin Pharmaceutical Company of Iran and intervention 2: consumption of famotidine 40 mg tablets of Ratiopharm GmbH of Germany. This study will be repeated on fasting volunteers in a cross-sectional manner with an interval of one week.

Main outcome variables

Maximum plasma concentration of famotidine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057495N12**
Registration date: **2023-12-19, 1402/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-19, 1402/09/28**
Update count: **0**

Registration date

2023-12-19, 1402/09/28

Registrant information

Name
Monireh Jalalipour

Name of organization / entity
Nikazma Pars Alborz company

Country
Iran (Islamic Republic of)

Phone
+98 26 3731 8748

Email address
info@naplab.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-16, 1402/09/25

Expected recruitment end date

2024-12-15, 1403/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Bioequivalence study of famotidine 40 mg tablets of Ramopharmin pharmaceutical company compared to Famotidine 40 mg of Ratiopharm GmbH in Germany on healthy volunteers.

Public title
Bioequivalence study of famotidine 40 mg tablet
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy volunteer between 18 and 55 years old. Body mass index less than 30 kg per square meter. All candidates must be non-smokers.
Exclusion criteria:
Blood pressure less than 90 on 60 mm Hg or more than 140 on 90 mm Hg. Consumption of any drug, alcohol or tobacco within 2 weeks before receiving the drug
Age
From **18 years** old to **55 years** old
Gender
Both

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: **30**

Randomization (investigator's opinion)
Not randomized
Randomization description
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
Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences
Street address
Institute of Pharmaceutical Sciences, Faculty of Pharmacy, Tehran University of Medical Sciences, Porsina Street
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2023-12-10, 1402/09/19
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.121

Health conditions studied

1

Description of health condition studied
In this research, no disease is studied.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maximum plasma concentration of famotidine
Timepoint
Before taking the medicine and: 20, 40, 60, 80, 100, 120, 150, 180, 240, 300, 360, 420, 600 and 720 minutes after taking the medicine.
Method of measurement
Liquid chromatography-mass spectrometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: includes the oral consumption of famotidine 40 mg tablets manufactured by Ramopharmin Pharmaceutical Company of Iran on 24 fasting healthy volunteers. 5 ml of blood was taken from the volunteers at time intervals before taking the drug and: 20, 40, 60, 80, 100, 120, 150, 180, 240, 300, 360, 420, 600 and 720 minutes after taking the drug. can be The cross-over study consists of two phases (oral administration of one 40 mg famotidine tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). The plasma concentration of famotidine is determined by liquid chromatography-mass spectrometry.
Category
Other

2

Description
Intervention group 2: includes the oral consumption of

famotidine 40 mg tablets of Ratiopharm GmbH, Germany, on 24 fasting healthy volunteers. 5 ml of blood was taken from the volunteers at time intervals before taking the drug and: 20, 40, 60, 80, 100, 120, 150, 180, 240, 300, 360, 420, 600 and 720 minutes after taking the drug. can be The cross-over study consists of two phases (oral administration of one 40 mg famotidine tablet per study and 2 times in total) with a one-week washout period (when the drug is completely removed from your blood). The plasma concentration of famotidine is determined by liquid chromatography-mass spectrometry.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Nik Azma Pars Alborz Laboratory

Full name of responsible person
Monireh Jalalipour

Street address
No. 419, Azadegan Square, Imam Khomeini Boulevard

City
Mahdasht Karaj

Province
Alborz

Postal code
3188913179

Phone
+98 26 3731 8748

Email
info@naplab.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ramopharmin Pharmaceutical Company

Full name of responsible person
Afsane Sabeti

Street address
In front of Azadi settlement, Valiasr St., Mina Glassmaking St.,Kilometer 4 of Karaj Special Road

City
Tehran

Province
Tehran

Postal code
1398834111

Phone
+98 21 4453 6020

Email
info@ramopharmin.com

Grant name

Grant code / Reference number

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

Title of funding source
Ramopharmin 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
Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

Position
Responsible Pharmacist

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
No. 419, Azadegan Square, Imam Khomeini Boulevard

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Person responsible for scientific inquiries

Contact

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Monireh Jalalipour

Position
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Person responsible for updating data

Contact
Name of organization / entity
Nik Azma Pars Alborz laboratory
Full name of responsible person
Monireh Jalalipour
Position
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Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available