

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

City

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Province

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Nik Azma Pars Alborz laboratory

Full name of responsible person

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
Responsible Pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No. 419, Azadegan Squar, Imam Khomeini Boulevard
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Province
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Postal code
3188913179

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