

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

In vivo study of famotidine tablet 40 mg, iranian product compare to the brand one on healthy volunteers

Protocol summary

Study aim

The aim of these studies is to compare the absorption of two formulations of the same drug (famotidine oral tablet 40 mg).

Design

Bioequivalence studies (bioequivalence) of famotidine 40 mg tablets manufactured by Aria Pharmaceutical Company compared to famotidine 40 mg manufactured by Joint Stock Company of Belarus include in vivo tests after administration to 24 healthy human volunteers with ethical approval and covered by liability insurance. .

Settings and conduct

On-site study: Nik Azma Pars Alborz Company (collaborating laboratory of the honorable Food and Drug Organization in the field of analysis of pharmaceutical and supplement products) The week is the washout period (when the drug is completely out of your blood). Each stage lasts for 12 hours. The total duration of participation of the candidates in both stages of this study will be a total of 24 hours, In the first stage of the study, you will be randomly assigned to one of the following two groups: group one consumes formula A and group two consumes formula B. Formulas A and B are products in the form of tablets produced in Iran and Belarus.

Participants/Inclusion and exclusion criteria

A: Entry criteria: - Be between 18 and 50 years old. - All candidates must be non-smokers. - The body mass index (BMI) of the candidate must be less than 30 kg/m². B: Non-entry criteria: - Volunteers with blood pressure lower than 60.90 mm Hg or higher than 90.90 mm Hg. - Candidates should refrain from smoking, consuming alcohol, caffeine (including coffee, cocoa, tea, cola drinks) 48 hours before the start of the study.

Intervention groups

The volunteers were in the age group of 18 to 50 years and were healthy and non-smokers. The study started fasting The study will be cross-over with a washing time of one week.

Main outcome variables

C max, t max, AUC

General information

Reason for update

Acronym

IVSF

IRCT registration information

IRCT registration number: **IRCT20230222057495N1**

Registration date: **2023-03-05, 1401/12/14**

Registration timing: **prospective**

Last update: **2023-03-05, 1401/12/14**

Update count: **0**

Registration date

2023-03-05, 1401/12/14

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

2023-04-03, 1402/01/14

Expected recruitment end date

2023-09-04, 1402/06/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo study of famotidine tablet 40 mg, iranian product compare to the brand one on healthy volunteers

Public title

In vivo study of famotidine tablet 40 mg

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 50 years Non smoking BMI below 30 kg/m2

Exclusion criteria:

Blood pressure below 90/60 or more than 140/90 mmHg
Smoking person (more than 10 /day) Using any kinds of medicine, alcohol or opioids during 2 weeks before starting the study

Age

From **18 years** old to **50 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**

Every sample, is obtained during 15 time intervals sampling, as 5 cc, from each volunteer. This is repeated two times (totally 30 samples from every volunteers)

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Pharmaceutical science Institute 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

2023-03-01, 1401/12/10

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.132

Health conditions studied**1****Description of health condition studied**

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Famotidine plasma concentrations

Timepoint

0 , 20 , 40 , 60 , 80 , 100 , 120 , 150 , 180 , 240 , 300 , 360, 420, 600 , 720 minutes after dose

Method of measurement

By HPLC- UV analytical instrument

Secondary outcomes**1****Description****Timepoint****Method of measurement****2****Description****Timepoint****Method of measurement****Intervention groups****1****Description**

Intervention group: The study consists of two phases (taking a famotidine 40 mg tablet orally at each study time, for a total of 2 times) with a one-week washout period (when the drug is completely out of your blood). Each stage lasts for 12 hours. You must fast for 10 hours before the start of each stage. On the morning of the study, you must be present at the place of the study at

7:00 a.m. to have an angiocath installed on your arm and for 12 hours. It will remain on your hand. 5 ml of blood before taking the medicine and during sampling times in minutes: 20, 40, 60, 80, 100, 120, 150, 180, 240, 300, 360, 420, 600, 720 will be taken from you (15 times in total). With a gap of one week after receiving the first drug, the candidates must go to receive another drug and all these steps will be repeated. The total duration of participation of the candidates in both stages of this study will be a total of 24 hours, during which the candidates are covered by Pasargad insurance and financially supported by Aria Pharmaceutical Company (as the employer in this study). In the first stage of the study, you will be randomly assigned to one of the following two groups: group one consumes formula A and group two consumes formula B. Formulas A and B are products in the form of tablets produced in Belarus and Iran.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nikazma Pars Alborz Laboratory

Full name of responsible person

Monireh Jalalipour

Street address

No. 419, Imam Khomeini Blvd., Azadegan Square, Alborz, Karaj, Mahdasht

City

Mahdasht Karaj

Province

Alborz

Postal code

3188913179

Phone

+98 26 3731 3406

Email

info@naplab.it

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Aria Pharmaceutical Company

Full name of responsible person

Roxana Nezami

Street address

Kilometer 17 of Karaj Special Road, 61st (Darupakhsh) St., corner of Autobahn Bridge, Aria Pharmaceutical Company

City

Tehran

Province

Tehran

Postal code

13971133111

Phone

+98 21 4498 1081

Email

info@aryapharm.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Aria 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

Nikazma Pars Alborz

Full name of responsible person

Monireh Jalalipour

Position

Technical Pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No. 419, Imam Khomeini Blvd., Azadegan Square, Alborz, Karaj, Mahdasht

City

Karaj Mahdasht

Province

Alborz

Postal code

3188913179

Phone

+98 26 3731 8748

Email

info@naplab.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Nikazma Pars Alborz

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, Imam Khomeini Blvd., Azadegan Square,
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Person responsible for updating data

Contact

Name of organization / entity

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Email

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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