Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Bioequivalance study of Famotidine 40 mg tablets manufactured by Fatak Chemie pars pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with famotidine tablets manufactured by Ratiopharm.

Protocol summary

Study aim

Comparing pharmacokinetics parameters of Fatak chemie pars Famotidine 40 mg tablets and Famotidine 40 mg tablet of Ratiopharm German.

Design

Bioequivalance study insists of one 24 healthy volunteers group. This group itself randomly divided to two 12 volunteers sub-groups. The first sub-groups administrated reference drug and the second sub-groups administrated generic or test drugs. The bioequivalance study is performed as cross over double blind within 1-2 weeks.

Settings and conduct

Bioequivalance Famotidine 40mg study will be performed under physician since 7 Am until 7 Pm. This study is carried out as a cross over double blind investigation. The blind person include volunteers, administrator and analyst.

Participants/Inclusion and exclusion criteria

Acceptance criteria: Healthy liver,Healthy kidney,Volunteers should not be too fat or too thin and their weight index should be in the appropriate range
Rejection criteria: Smokers and pregnancy.

Intervention groups

Intervention consists of administration of one Famotidine 40 mg tablet of FATAK CHIMIE PARS company as TEST PRODUCT to the first twelve group in this cross-study and simultaneously administration of one Famotidine 40 mg tablet of RATIOPHARM company as REFERENCE PRODUCT to the second twelve group as control group.

Main outcome variables

Plasma concentration of famotidine is the main consequence, its concentration at Tmax reaches about 200 ng/mL and its measurement range is from 10ng / mL to 700ng / mL.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200513047423N5**
Registration date: **2021-11-29, 1400/09/08**
Registration timing: **retrospective**

Last update: **2021-11-29, 1400/09/08**
Update count: **0**

Registration date

2021-11-29, 1400/09/08

Registrant information

Name
Amir Mehdizadeh

Name of organization / entity
Ofogh pajo

Country
Iran (Islamic Republic of)

Phone
+98 21 6673 8727

Email address
ofoghfarmed.lab@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-05, 1400/08/14

Expected recruitment end date

2021-11-26, 1400/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Bioequivalance study of Famotidine 40 mg tablets manufactured by Fatak Chemie pars pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with famotidine tablets manufactured by Ratiopharm.

Public title
Bioequivalance study of Famotidine 40 mg
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy liver Healthy kidney Volunteers should not be too fat or too thin and their weight index should be in the appropriate range
Exclusion criteria:
Out of age ranges smoking pragnancy
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **1**
Each volunteers has been administrated one reference drug and next time test drugs.
Randomization (investigator's opinion)
Randomized
Randomization description
We designate to 24 healthy volunteers one number between 1 and 24. Extraction of 12 numbers is carried out using https://kitset.ir/numbers/random#random-number-form. These first 12 random numbers create the first group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The main investigator creates a table using randomization and divides 24 healthy volunteer in 2 groups which only he knows the details of group. Test and reference drugs are packaged in special envelopes that administrator and volunteers are blinded regarding to the kind of drugs. Volunteers, administrator (health care professional) and analyst are blinded regarding to reference and test drugs.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Apart 14, No. 65, Razi St., Enqelab Ave.
City
Tehran
Province
Tehran
Postal code
1133713144
Approval date
2021-10-05, 1400/07/13
Ethics committee reference number
IR.IUMS.REC.1400.625

Health conditions studied

1

Description of health condition studied
Bioequivalance Famotidine 40 mg
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
plasma concentration changing after administration of Famotidine tablet.Plasma concentration of famotidine at Tmax reaches about 200 ng/mL and its measurement range is from 10ng / mL to 700ng / mL
Timepoint
Initial blood sampling is performed before drug administration to obtain blank plasma chromatogram of each volunteers. Hence the Tmax of Famotidine is between 1 and 3 hours, so it is needed to have 5 blood sampling before Tmax. This period of time is called absorption phase. In the elimination phase (after Tmax) blood sampling carry out each hours.
Method of measurement
In this study, the variable is plasma concentration of famotidine. High performance liquid chromatography is used to determine the concentration of famotidine in plasma.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: One Famotidine 40 mg tablet manufactured by Fatak chemie pars company (Test drug) is administrated to each of 12 healthy volunteer of group 1.
Category
Behavior

2

Description
Intervention group 2: One Famotidine 40 mg tablets manufactured by Ratiopharm German company is administrated to each o 12 healthy volunteers of group 2.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Ofoqh pharmed
Full name of responsible person
Dr Amir mehdizadeh
Street address
No. 65, Razi Ave, Enqhelab Ave
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1133713144
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a_mehdizadeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fatak chemie pars Pharmacy
Full name of responsible person
Dr Reza hadavi
Street address
No13, Second alley, Pakestan Ave, Beheshti Ave, Tehran
City
Tehran
Province
Tehran
Postal code
1531636319
Phone
+98 21 8873 8441
Email
info@fatakchemie.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Fatak chemie pars
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
Ofoqh pharmed labratory
Full name of responsible person
Dr Amir mehdizahed
Position
Responsible pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr setareh Akbari
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work

Medical Ethics

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Person responsible for updating data

Contact

Name of organization / entity

Ofoqh pharmed

Full name of responsible person

Amir mehdizadeh

Position

Responsible pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Demography tables of volunteers including group 1 and 2 have been shared in bioequivalance report.

When the data will become available and for how long

The results of bioequivalance study of Famotidine tablets will be shared after accepting by Iranian food and drug organization.

To whom data/document is available

The results of bioequivalance study of Famotidine tablets will be accessed by expert by Iranian food and drug organization and financial supporter.

Under which criteria data/document could be used

To promotion of result of investigation, The results will be shared with eager.

From where data/document is obtainable

1-Iranian food and drug organization 2-Ofogh farmed laboratory

What processes are involved for a request to access data/document

To complied of educational filed of eager to result of investigation.

Comments