

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Bioequivalence evaluation of Fexofenadine Tablet 180 mg manufactured by Raha pharmaceutical company

Protocol summary

Study aim

Bioequivalence study of Fexofenadine 180 mg Tablet manufactured by Raha Pharmaceutical company

Design

Clinical trials of single blind design of 24 volunteers with controlled group.

Settings and conduct

After selecting the volunteers, Fexofenadine manufactured by Raha pharmaceutical company from Iran and Fexofenadine manufactured by Sanofi Aventis company will be prescribed to them orally in two doses with an interval of 7 days. For example, if in the first period of the drug administration, the volunteer received the drug manufactured by Raha pharmaceutical company, in the next turn, the volunteer will receive drug manufactured by Sanofi Aventis company. Each time the amount of 6 cc of blood will be taken before drug administration and at times of 0, 33/0, 66/0, 1, 33/1, 66/1, 2, 33/2, 66/2, 3, 5/3, 4, 5, 6, 8, 10, 12, 16, 24, 48 hour after the medication is prescribed. The next sampling will 7 days later. In the second time, similar to the first time of drug administration, blood sampling will be done. Finally, the amount of drug in each sample is determined by HPLC equipment.

Participants/Inclusion and exclusion criteria

Healthy volunteers, no history of diseases affecting the pharmacokinetic processes of the drug, no chronic or acute use of any drug at least 1 week before starting the study

Intervention groups

Volunteers will be divided into two groups: On the first week, group one will receive Fexofenadine manufactured by Raha Pharmaceutical company and group number two will receive Fexofenadine manufactured by Sanofi Aventis company. On the second week, group number one will receive Fexofenadine manufactured by Sanofi Aventis company and group number two will receive Fexofenadine manufactured by Raha Pharmaceutical company (cross over)

Main outcome variables

Maximum plasma concentration; area under the curve; the time taken to reach maximum plasma concentration

General information

Reason for update

Acronym

BEF

IRCT registration information

IRCT registration number: **IRCT20200625047913N6**

Registration date: **2021-05-16, 1400/02/26**

Registration timing: **prospective**

Last update: **2021-05-16, 1400/02/26**

Update count: **0**

Registration date

2021-05-16, 1400/02/26

Registrant information

Name

Tayebeh Ghari

Name of organization / entity

Hezareh Sevom Futuristic Pharmacist Company

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 2343

Email address

info@hezareh-co.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-19, 1400/03/29

Expected recruitment end date

2021-07-20, 1400/04/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence evaluation of Fexofenadine Tablet 180 mg manufactured by Raha pharmaceutical company

Public title
Bioequivalence evaluation of Fexofenadine Tablet 180 mg manufactured by Raha pharmaceutical company

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
18 to 45 years old Sex: Males and/or non-pregnant, non-lactating females Body mass index: 18.5 to 24.9 weight in kg/(height in meter) Able to communicate effectively with study personnel and willingness to follow the protocol requirements as evidenced by written informed consent A physical examination with no clinically significant finding and laboratory normal tests Do not take any chronic or acute medication for at least 1 week before the start of the study No history of diseases affecting the pharmacokinetic processes of the drug
Exclusion criteria:
History of allergic responses to Fexofenadine or other related drugs, or any of its formulation ingredients Have significant diseases (which might compromise the haemopoietic, gastrointestinal, renal, hepatic, cardiovascular, respiratory, central nervous system, diabetes, psychosis or any other body system) or clinically significant abnormal findings during screening Smokers who smoke 10 or more cigarettes per day or 20 or more biddies per day or those who cannot refrain from smoking during the study period History or evidence of drug dependence or of alcoholism or of moderate alcohol use History of difficulty with donating blood or difficulty in accessibility of veins Volunteers who have received a known investigational drug within five elimination half life of the administered drug prior to the initial dose of study drug or who have participated in a clinical drug study or bioequivalence study within 90 days prior to the initial dose of study drug, whichever is greater Found positive in urine test for drugs of abuse done before check-in of period History of difficulty in swallowing, or of any gastrointestinal disease which could affect drug absorption

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)

N/A

Randomization description
Blinding (investigator's opinion)
Single blinded

Blinding description
به داوطلبین یک هفته داروی تست و هفته بعد داروی رفرانس تجویز می شود. داوطلبین مطلع نیستند که هر هفته کدام دارو را دریافت می کنند.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics committee of institute of pharmaceutical science of Tehran University of Medical Sciences
Street address
16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences, 2nd floor, Unit 1-219, Tehran- Iran.
City
تهران
Province
Tehran
Postal code
۱۴۱۷۶۱۴۴۱۱

Approval date
2021-05-14, 1400/02/24

Ethics committee reference number
IR.TUMS.TIPS.REC.1400.037

Health conditions studied
1
Description of health condition studied
-
ICD-10 code
-
ICD-10 code description
-

Primary outcomes
1
Description
Plasma concentration
Timepoint
0, 33/0, 66/0, 1, 33/1, 66/1, 2, 33/2, 66/2, 3, 5/3, 4, 5, 6, 8, 10, 12, 16, 24 hr 48

Method of measurement

HPLC with fluorescence

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: Prescription of Fexofenadine 180 mg Tablet manufactured by Raha pharmaceutical company from Iran in the first week

Category

Other

2

Description

Control group: Prescription of Fexofenadine 180 mg Tablet manufactured by Sanofi Aventis company from Germany in the first week

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hezareh Sevom Futuristic Pharmacist Company

Full name of responsible person

Tayebeh Ghari

Street address

Unit 4, No. 81, Babak Bahrami st, After Zafar st, Tehran, Iran

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Tehran

Postal code

1968655815

Phone

+98 21 8865 2343

Email

tayebehghari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hezareh Sevom Futuristic Pharmacist

Full name of responsible person

Tayebeh Ghari

Street address

Unit 4, No 81, Babak Bahrami st, After Zafar st, Tehran, Iran.

City

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Province

Tehran

Postal code

1968655815

Phone

+98 21 8865 2343

Email

info@hezareh-co.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hezareh Sevom Futuristic Pharmacist

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Alborze University of medical sciences

Full name of responsible person

Faranak Salmannejad

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Alborze School of pharmacy, near Bahonar Hospital, Vali-e-asr st, Shora Blv, Karaj.

City

Karaj

Province

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3154686689

Phone

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salmannejad.f@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Alborze University of medical sciences

Full name of responsible person
Faranak Salmannejad

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
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Person responsible for updating data

Contact

Name of organization / entity
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Assistant professor

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Phone
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Email
salmannejad.f@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

from 1400

To whom data/document is available

People working in industry and academia

Under which criteria data/document could be used

People working in industry and academia

From where data/document is obtainable

Sending email to info@hezareh-co.com - Sending fax to 00982188208678 - Calling to 00982188652343 -

Responsible person: Tayebeh Ghari

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

Sending email to info@hezareh-co.com/ request evaluation/sending data

Comments