Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalance study of Fexofenadine 180 mg Tablets manufactured by Sana Med pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Telfast Tablets manufactured by Abidi-SANOFI

Protocol summary

Study aim

Comparing pharmacokinetics parameters of Fexofenadine 180 mg Tablets manufactured by Sana Med pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Telfast Tablets manufactured by SANOFI

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 Fexofenadine 180 mg 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: 1- Healthy liver 2- Healthy kidney 3- Volunteers should not be too fat or too thin and their weight index should be in the appropriate range Rejection criteria: 1- Smokers and pregnancy.

Intervention groups

Intervention consists of administration of one Fexofendine 180 mg tablet of Sana Med company as TEST PRODUCT to the first twelve group in this cross-study and simultaneously administration of one Telfast mg tablet of SANOFI company as REFERENCE PRODUCT to the second twelve group as control group.

Main outcome variables

Plasma concentration of Fexofenadine 180mg is the main consequence, its concentration at Tmax reaches about 800 ng/mL and its measurement range is from 50ng / mL to 2000ng / mL.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200513047423N6**
Registration date: **2022-01-05, 1400/10/15**
Registration timing: **prospective**

Last update: **2022-01-05, 1400/10/15**
Update count: **0**

Registration date

2022-01-05, 1400/10/15

Registrant information

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Amir Mehdizadeh
Name of organization / entity
Ofogh pajo
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Iran (Islamic Republic of)
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+98 21 6673 8727
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-28, 1400/11/08

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalance study of Fexofenadine 180 mg Tablets manufactured by Sana Med pharmaceutical company on 24 healthy volunteers and comparing pharmacokinetics results with Telfast Tablets manufactured by Abidi-SANOFI

Public title

Bioequivalance study of Fexofenadine 180 mg Tablets

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 pregnancy

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 Shahid Beheshti University of Medical Sciences

Street address

Apart 14, No. 65, Razi St., Enqelab Ave.

City

Tehran

Province

Tehran

Postal code

1133713144

Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.408

Health conditions studied

1

Description of health condition studied

Bioequivalance Fexofenadine 180 mg

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

plasma concentration changing after administration of Fexofenadine180 mg tablet.Plasma concentration of Fexofenadine at Tmax reaches about 800 ng/mL and its measurement range is from 50ng / mL to 2000ng / mL

Timepoint

Initial blood sampling is performed before drug administration to obtain blank plasma chromatogram of each volunteers. Hence the Tmax of Fexofenadine is between 1.5 and 2.5 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. Sampling is done in 24 and 48 hours

Method of measurement

In this study, the variable is plasma concentration of Fexofenadine. High performance liquid chromatography is used to determine the concentration of famotidine in plasma.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One Fexofenadine 180 mg tablet manufactured by Sana Med company (Test drug) is administrated to each of 12 healthy volunteer of group 1
Category
Behavior

2

Description
Intervention group: One Fexofenadine 180 mg tablets manufactured by Abidi-SANOFI 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sana Med
Full name of responsible person
Dr Malek marzban
Street address
No 1 , Hekmat Ave, Bozorgmehr Ave, valiasr Ave
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1416844983
Phone
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Email
info@sanamedpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Sana Med
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 mehdizadeh
Position
Responsible pharmacist
Latest degree
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Other areas of specialty/work
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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 bioequivalence report.
When the data will become available and for how long
The results of bioequivalence study of Fexofenadine tablets will be shared after accepting by Iranian food and drug organization.
To whom data/document is available
The results of bioequivalence study of Fexofenadine 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 pharmed research laboratory
What processes are involved for a request to access data/document
To complied of educational filed of eager to result of investigation.
Comments