

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Bioequivalence 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

Bioequivalence 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 bioequivalence study is performed as cross over double blind within 1-2 weeks.

##### Settings and conduct

Bioequivalence 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

##### 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

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**  
Bioequivalence 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**  
Bioequivalence 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

Bioequivalence Fexofenadine 180 mg

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

plasma concentration changing after administration of Fexofenadine 180 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

No. 65, Razi Ave, Enghelab Ave

#### City

Tehran

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#### Postal code

1133713144

#### Phone

+98 21 6673 8727

#### Email

a\_mehdizadeh@gmail.com

## 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1416844983

#### Phone

+98 21 6640 3568

#### 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

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Dr Farzad kobarfard

#### Position

Professor

#### Latest degree

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for updating data****Contact****Name of organization / entity**

Ofogh pharmed

**Full name of responsible person**

Ofogh pharmed

**Position**

Responsible pharmacist

**Latest degree**

Ph.D.

**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**