

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### Bioequivalence study of the Exemestane 25 mg tablets manufactured Iran hormone pharmaceutical Co.

#### Protocol summary

##### Study aim

En Demonstration of bioequivalence of Exemestane 25-mg tablet of Iran hormone with tablet manufactured by Pfizer after single dose administration.

##### Design

A single-group, not blinded, not randomized, bioequivalence clinical trial on 24 healthy volunteers.

##### Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. The number of 24 volunteer in the age range of 18-50years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken at 18 times point. Two week later, the process is repeated for the brand medicine

##### Participants/Inclusion and exclusion criteria

The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase ( $\gamma$ -GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form

##### Intervention groups

After taking a Exemestane 25-mg tablet from domestic company, 3 milliliters of blood will be collected from the volunteer in 18 times intervals for 72 hours. Two week later, the process is repeated for a brand sample tablet. The drug concentration is measured in plasma

##### Main outcome variables

Studying the Drug pharmacokinetic parameters including measuring the plasma concentrations for brand and test products, determining the desired and important

pharmacokinetic parameters in bioequivalence studies, AUCs, Tmax, Cmax, T1/2

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130313012810N41**

Registration date: **2024-11-12, 1403/08/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-11-12, 1403/08/22**

Update count: **0**

##### Registration date

2024-11-12, 1403/08/22

##### Registrant information

##### Name

Hamed Hamishehkar

##### Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1336 3311

##### Email address

hamishehkar.hamed@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-11-10, 1403/08/20

##### Expected recruitment end date

2024-11-15, 1403/08/25

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Bioequivalence study of the Exemestane 25 mg tablets manufactured Iran hormone pharmaceutical Co.

**Public title**

Exemestane tablet bioequivalence

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The weight range of participating candidates should be between 60-100 kg Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose. Volunteers who have agreed to an informed consent form. All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw

**Exclusion criteria:**

History of allergic or adverse reaction to Exemestane or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s) Smokers

**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**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Crossover

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Daneshgah St. Drug Applied Research Center

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665811

**Approval date**

2024-10-14, 1403/07/23

**Ethics committee reference number**

IR.TBZMED.REC.1403.598

**Health conditions studied**

**1**

**Description of health condition studied**

Bioequivalence study in healthy volunteers

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Plasma concentration of the drug

**Timepoint**

18 sampling time till 72 h

**Method of measurement**

Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group 1, which consists of 24 healthy and fasting volunteers, will receive a tablet with a dose of 25 mg manufactured by Iran hormone Pharmaceutical Company.

**Category**

N/A

**2**

**Description**

Intervention group 2, which consists of 24 healthy and

fasting volunteers, will receive a tablet with a dose of 25 mg manufactured by Pfizer Pharmaceutical Company.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Drug Applied Research Center, Tabriz University of Medical Sciences

**Full name of responsible person**

Hamed Hamishehkar

**Street address**

Drug Applied Research Center, Tabriz University of Medical Sciences

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hamishehkar.hamed@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran hormone

**Full name of responsible person**

Mehdi Amani

**Street address**

Km 11 Karaj Makhsous Road

**City**

Tehran

**Province**

Tehran

**Postal code**

1399813611

**Phone**

+98 21 4490 5517

**Email**

info@iranhormone.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran hormone

**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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Mehrdad Hamidi

**Position**

Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Zanjan University of Medical Sciences, Sobooti road, Zanjan, Zanjan Province

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**Contact**

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Zanjan University of Medical Sciences

**Full name of responsible person**

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**Position**

Zanjan

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor

**Latest degree**

Ph.D.

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**Web page address**

## 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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available