Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 (γ-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

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Email address

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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
Daneshghah 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

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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

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Tehran

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1399813611

Phone

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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

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Other areas of specialty/work

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Person responsible for updating data

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Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
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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