

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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, T_{max}, C_{max}, T_{1/2}

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

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone

+98 41 3336 3311

Email

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

City

Zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3342 0651

Email

hamidi@hidapharma.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Mehrdad Hamidi

Position

Zanjan

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

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

City

Zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3342 0651

Email

hamidi@hidapharma.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Drug Applied Research Center-Tabriz University of
Medical Science

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Phone

+98 41 3336 3181

Fax**Email**

hamishehkar.hamed@gmail.com

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