Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence study of Bicalutomide 50 mg tablet (Iran Hormone) versus Casodex® 50 mg (AstraZeneca-Brand) Tablet in healthy volunteers

Protocol summary

Study aim

Bioequivalence study of Bicalutomide 50 mg tablet (Iran Hormone) versus Casodex® 50 mg (AstraZeneca-Brand) Tablet in healthy volunteers

Design

Bioequivalence study, with control group, double-blind, randomized, on 24 volunteers, from each volunteer 20 blood samples were taken. Sealed envelope is used for randomization.

Settings and conduct

The subject of this biopharmaceutical and pharmacokinetic study is the location of Blood collection center of Tam Pouya Company located in Tehran. The study was blinded to the study participants by removing the drugs from the original package and placing the test and reference drugs in the same package, and the participants were not aware of the type of drug they were taking.The crossover design is such that the Iranian drug will be prescribed to the first group in the first week and to the second group in the second week. Brand medicine, on the contrary, Iranian medicine will be prescribed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: general health (liver, heart and kidneys), body mass index (18-28), informed consent, age (50-18) Exclusion criteria: smoking, history of cardiovascular disease, history of liver disease and Renal, alcohol and drug addiction, history of allergy to Bicalutomide

Intervention groups

Intervention group: Receives one tablet of test drug (Bicalutomide 50 mg tablet pharmaceutical company Iran Hormone). Control group: Receives one reference medicine tablet (Casodex® 50 mg Tablet (AstraZeneca-Brand).

Main outcome variables

Determination of blood concentration profile parity of brand drug with generics.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220111053692N15**
Registration date: **2023-11-11, 1402/08/20**
Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**
Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

Bardia Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 4707

Email address

info@tampouya.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-02, 1402/09/11

Expected recruitment end date

2023-12-09, 1402/09/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Bicalutomide 50 mg tablet (Iran Hormone) versus Casodex® 50 mg (AstraZeneca-Brand) Tablet in healthy volunteers

Public title

Bioequivalence study of Bicalutomide 50 mg

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 55 years old Weight in range of 10 % proper body weight All volunteers should be in a good health condition on the basis of medical history ,physical examination , routine blood test. Possessing negative test for hepatitis B surface antigen (HBs-Ag), Antihepatitis-C antibody (anti-HCV) and anti-HIV. Gender: male

Exclusion criteria:

Volunteers with hypersensitivity to Bicalutomide were excluded. Those with known history of drug abuse. alcohol consumer or cigarette smokers. Taking medications that have drug interactions with Bicalutomide until one month before studying. Disinclination to take the test Blood donation or blood loss of more than 200 ml in the past month

Age

From **18 years** old to **55 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly allocate people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are placed in random order. After entering the study, each candidate will take an envelope, numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 (test product) and group B will receive intervention 2 (reference product) and after the first period, the interventions of the two groups will be moved for the second period

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a Double-blind (participant) clinical trial. Bicalutomide and Casodex tablets are removed from the package by the administrator and placed in similar and coded cans. Medicine and placebo are the same in terms of the method of administration

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of The Institute of Pharmaceutical Sciences,Tehran University of Medical Sciences

Street address

Research Institute of Pharmaceutical Sciences, second floor of the old building, Faculty of Pharmacy, Enqelab Square, 16 Azar St.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.TUMS.VCR.REC.1398.1023

Health conditions studied

1

Description of health condition studied

Bioequivalence study of Bicalutomide 50 mg tablet (Iran Hormone) versus Casodex® 50 mg (AstraZeneca-Brand) Tablet in healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug concentration in plasma samples

Timepoint

In times 0, 1, 2, 3, 5, 7, 9, 12, 15, 24, 36, 48, 72, 168, 336, 504, 672 Hours after the start of the intervention

Method of measurement

chromatography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Receives one

tablet of test drug (Bicalutomide 50 mg tablet pharmaceutical company Iran Hormone). Blood samples were taken from the volunteers for 672 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector.

Category

Other

2

Description

Control group: Receives one reference medicine tablet (Casodex® 50 mg Tablet (AstraZeneca-Brand). Blood samples were taken from the volunteers for 672 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tam Pouya Consulting & Research Company

Full name of responsible person

Bardia Jamali

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No. 7 ,Navard Ave ,17 Shahrivar St., 5th Km Fat`h Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran Hormone pharmaceutical Co.

Full name of responsible person

Dr. Mehdi Amani

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ground floor, No. 255, Lashgari Highway, 27th Street, Karaj Special Road

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Email

info@iranhormone.com

Web page address

https://www.iranhormone.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran Hormone pharmaceutical Co.

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tam Pouya Consulting & Research Company

Full name of responsible person

Bardia Jamali

Position

manager

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
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