Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

In- Vivo Bioequivalence study of Bicalutamide tablet 150 mg Sobhan Oncology (Bicalutamide 150mg) with brand drug (CASODEX® 150 mg AstraZeneca) in Iranian healthy volunteers

Protocol summary

Study aim

In- Vivo Bioequivalence study of Bicalutamide tablet 150 mg Sobhan Oncology (Bicalutamide 150mg) with brand drug (CASODEX® 150 mg AstraZeneca) in Iranian healthy volunteers

Design

In-vivo bioequivalence study of Bicalutamide tablet 150 mg Sobhan Oncology in compared with reference drug ((CASODEX® 150 mg AstraZeneca, UK)). The single blind, Cross-over, two period, two groups (Intervention and control) and randomized (paper lottery randomization method) study with one week wash-out time.

Settings and conduct

This study is carried out in Simin Baspar Tayf Gostar Company located in Tabriz. The study population is 24 healthy Iranian volunteers.This study is a single blind study and by taking out the drugs from the existing packaging, the volunteers will not know the time of receiving the test drug and the brand. This study is a cross over study that is performed in two time periods of 72 hours with a one-week wash-out period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: participants are between 18-60 years old, Normal body mass index (BMI in the range of 18-28) Non Inclusion criteria: smoking; Have a history of heart, kidney and liver disease, Pregnancy, Drug addiction

Intervention groups

Single dose Bicalutamide tablet 150 mg Sobhan Oncology Pharmaceuticals. Control group:Single dose brand drugs (CASODEX® 150 mg AstraZeneca, UK)

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N45**
Registration date: **2021-11-16, 1400/08/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-16, 1400/08/25**
Update count: **0**

Registration date

2021-11-16, 1400/08/25

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2022-09-11, 1401/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of Bicalutamide tablet 150

mg Sobhan Oncology (Bicalutamide 150mg) with brand drug (CASODEX® 150 mg AstraZeneca) in Iranian healthy volunteers

Public title
In-vivo Bioequivalence Test of Bicalutamide tablet with brand drugs (CASODEX® 150 mg AstraZeneca UK).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General health Body mass index between18-28 Informed consent Being at the age of 18-60 years old
Exclusion criteria:
Smoking History of cardiovascular disease History of liver or kidney disease Pregnancy Alcohol & Drug addiction History of hypersensitivity
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
For this reason, A 24- person group will be selected and divided to two 12-person groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.
Blinding (investigator's opinion)
Single blinded
Blinding description
Candidates are not aware of receiving the test drug or brand one. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Test and brand drug (Bicalutamide tablets) are withdrawal from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about the types of receiving drugs (test or brand).
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Tabriz University of Medical Sciences
Street address
Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-08-02, 1400/05/11
Ethics committee reference number
IR.TBZMED.REC.1400.469

Health conditions studied

1

Description of health condition studied
Plasma drug concentration
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma drug concentration
Timepoint
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours after prescribing the table
Method of measurement
High Performance Liquid Chromatography tandem mass spectroscopy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: they will receive one test drug tablet (Bicalutamide tablet 150 mg Sobhan Oncolog Pharmaceuticals). Plasma samples will be taken from the volunteers during 72 hours at the mentioned times after drug administration and the concentration of Bicalutamide in plasma samples will be measured by liquid chromatography with mass spectroscopy detector.
Category
Treatment - Other

2

Description
Control group: will receive one test drug table (CASODEX® 150 mg AstraZeneca). Plasma samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Bicalutamide in plasma samples will be measured by liquid chromatography with mass spectroscopy detector.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Simin Baspar Teyf Gostar Company

Full name of responsible person
Javad Shokri

Street address
No.48, Ferdos square

City
Tabriz

Province
East Azarbaijan

Postal code
5167874434

Phone
+98 41 3384 2724

Email
Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sobhan Oncology Pharmaceutical CO.

Full name of responsible person
Mitra Hajarian

Street address
No. 11, 5th Alley, Bucharest Ave,Argentina Sq, Tehran

City
Tehran

Province
Tehran

Postal code
7636318451

Phone
+98 21 8848 0161

Email
info@sobhanpharma.com

Grant name

Grant code / Reference number

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

Title of funding source
Sobhan Oncology 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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Javad Shokri

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah

City
Tabriz

Province
East Azarbaijan

Postal code
5166414766

Phone
+98 41 3334 8489

Email
Shokri.j@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Javad Shokri

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah

City
Tabriz

Province
East Azarbaijan

Postal code

5166414766

Phone

+98 41 3334 8489

Email

Shokri.j@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Phone

+98 41 3334 8489

Email

Shokri.j@gmail.com

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

These date are as secure between researcher and related industries

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

Yes - There is a plan to make this available

Title and more details about the data/document

Only protocol and methods of study are sharable

When the data will become available and for how long

Only protocol and methods of study are shareable.

To whom data/document is available

Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used

Projects information's for any publications is not allowed.

From where data/document is obtainable

By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document

This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email aft

Comments