Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

In- Vivo Bioequivalence study of Abiraterone tablet 500 mg Actero Middle East Pharma (Abiraterone ACTe® 500 mg Tab.) with brand drug (ZYTIGA® 500 mg, Janssen Biotech, Germany) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Abiraterone tablet 500 mg Actro Middle East Pharma with brand drug (ZYTIGA® 500 mg, Janssen Biotech, Germany) in Iranian healthy volunteers.

Design

In-vivo bioequivalence study of Abiraterone tablet 500 mg Middle East Pharma in comparison with reference drug (ZYTIGA® 500 mg, Janssen Biotech, Germany). 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, Tabriz, Iran. 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 two-week wash-out period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-55 years old; body mass index (BMI) in the range of 18-28. Exclusion criteria: history of heart, kidney and liver disease; pregnancy; drug addiction; smoking

Intervention groups

Single dose Abiraterone tablet 500 mg Actro Middle East Pharma. Control group: brand drugs (ZYTIGA® 500 mg, Janssen Biotech, Germany)

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N57**
Registration date: **2022-04-05, 1401/01/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-05, 1401/01/16**
Update count: **0**

Registration date

2022-04-05, 1401/01/16

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

2022-03-26, 1401/01/06

Expected recruitment end date

2022-10-28, 1401/08/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of Abiraterone tablet 500

mg Actero Middle East Pharma (Abiraterone ACTe® 500 mg Tab.) with brand drug (ZYTIGA® 500 mg, Janssen Biotech, Germany) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence Test of Abiraterone tablet 500 mg Actero Middle East with brand drug (ZYTIGA® 500 mg, Janssen Biotech, Germany)
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 A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug
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 purpose, A 24- persons group will be selected and divided to two 12-persons 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 drugs are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test drug.
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
Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-11-15, 1400/08/24
Ethics committee reference number
IR.TBZMED.REC.1400.733

Health conditions studied

1

Description of health condition studied
Bio equivalence test
ICD-10 code
ICD-10 code description

Primary outcomes

1

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

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One test tablet (Abiraterone tablet 500 mg produced by Actro Middle East Pharma) will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector
Category
Treatment - Other

2

Description
Control group: One Reference tablet ZYTIGA® 500 mg, Janssen Biotech, Germany will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of drug 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

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Tabriz

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5167874434

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Actero middle east Pharm Co.

Full name of responsible person
Sanaz Golbabaei

Street address
No 58, 6th St, Balouchestan St, Tehran, Iran

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Tehran

Province
Tehran

Postal code
1446863914

Phone
+98 21 4431 9003

Email
info@actoverco.com

Grant name

Grant code / Reference number

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

Title of funding source
Actero middle east Pharm 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

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Person responsible for scientific inquiries

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Person responsible for updating data

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Master
Other areas of specialty/work
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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
All information and data of the study will remain secured based on the agreement established between researcher and drug producer.
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
The access to data will be possible after finishing of project (almost 6 months after receiving of IRCT Code).
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
These information are confidential and be under disposal of the project's contractor. Upon request, the information will be accessed to the applicant by the Executor's email after receiving contractor's consent.
Comments