Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

In-vivo Bioequivalence Study of Palbociclib 125 mg Hard Capsules of The Test Drug (IBRACT®, 125 mg Cap., Actero Pharma, Iran) in Compared with The Reference Drug (IBRANCE® 125 mg Cap., Pfizer Inc. Ireland) In Iranian Healthy Volunteers

Protocol summary

Study aim
In-vivo Bioequivalence Study of Palbociclib 125 mg Hard Capsules of The Test Drug (IBRACT®, 125 mg Cap., Actero Pharma, Iran) in Compared with The Reference Drug (IBRANCE® 125 mg Cap., Pfizer Inc. Ireland) In Iranian Healthy Volunteers

Design
Bioequivalence study, crossover, single-blinded, 24 healthy volunteers. Simple randomization was used for randomization

Settings and conduct
The study is a single-blinded (Volunteers), cross-over and fed, and on two series of healthy volunteers. The study will be done in two periods (72h). The interval between these two periods is 2 weeks. In the first round of the study, the candidates were divided into two groups the first group received a test tablet and the second group received a brand tablet. Blood samples are collected immediately before and after drug administration by volunteers. Then, drug extraction is done and samples are ready for analysis. Sampling is performed in Radin laboratory in Tabriz.

Participants/Inclusion and exclusion criteria
General Health (Liver, Heart, and Kidney), Body Mass Index (18-30), informed consent, Age (18-60years old)

Intervention groups
Intervention group 1:(IBRANCE® 125 mg, Pfizer Inc. Ireland) as a reference Intervention group 2: (IBRACT®, 125 mg Cap., Actero Pharma, Iran) as a test

Main outcome variables
Maximum drug concentration, Time to reach maximum drug concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046010N113**
Registration date: **2024-08-05, 1403/05/15**
Registration timing: **prospective**

Last update: **2024-08-05, 1403/05/15**
Update count: **0**

Registration date
2024-08-05, 1403/05/15

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
2024-08-22, 1403/06/01

Expected recruitment end date
2025-08-23, 1404/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

In-vivo Bioequivalence Study of Palbociclib 125 mg Hard Capsules of The Test Drug (IBRACT®, 125 mg Cap., Actero Pharma, Iran) in Compared with The Reference Drug (IBRANCE® 125 mg Cap., Pfizer Inc. Ireland) In Iranian Healthy Volunteers

Public title
In-vivo Bioequivalence Study of (IBRACT®, 125 mg Cap., Actero Pharma, Iran)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
General Health (Liver, Heart, and Kidney) Body Mass Index (18-30) Informed consent Age (18-60years old)
Exclusion criteria:
Smoking History of cardiovascular disease History of liver and kidney disease Alcoholism and Narcoticism History of allergy to Palbociclib
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **22**
Blood sample
Randomization (investigator's opinion)
Randomized
Randomization description
People in the mentioned age group are invited to participate through the advertisement. People are then checked for health and healthy volunteers are identified. Each candidate is assigned a number from 1 to 24. The numbers are written on a plastic ball poured into a container and mixed. The balls are then removed randomly from the container. The first 12 no.s are considered as (first sequence: test medicine) and the second 12 no.s are considered as (second sequence: originator brand recipient). The volunteers don't have any information about taking the test drug or brand drug
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blinded clinical trial (volunteers). Test and Originator brand's tablets 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 dosage form.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences ethics committe
Street address
No. 48, Ferdows street, Ferdowsi Sq.
City
Tabriz
Province
East Azarbaijan
Postal code
5167874434
Approval date
2024-07-22, 1403/05/01
Ethics committee reference number
IR.TBZMED.REC.1403.309

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers and drug concentration in plasma is determined.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration
Timepoint
0، 1، 2 ،4، 6، 8، 10، 12، 24، 48، 72 h after drug administration
Method of measurement
Liquid Chromatography Mass-Mass

Secondary outcomes

1

Description
Time to reach maximum plasma concentration
Timepoint
After intervention
Method of measurement
Time to reach the maximum drug concentration in plasma is recorded.

2

Description
Extent of absorption

Timepoint
After intervention
Method of measurement
Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group: single dose, one oral capsule (IBRANCE® 125 mg, Pfizer Inc. Ireland) as a reference product. after washout period, the volunteers received Palbociclib 125 mg Hard Capsules of The Test Drug (IBRACT®, 125 mg Cap., Actero Pharma, Iran)
Category
Treatment - Drugs

2

Description
Intervention group: Single dose, one oral Palbociclib 125 mg Hard Capsules of The Test Drug(IBRACT®, 125 mg Cap., Actero Pharma, Iran) as test product. after washout period, the volunteers received (IBRANCE® 125 mg, Pfizer Inc. Ireland)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Radin laboratory
Full name of responsible person
Bahram Ataii
Street address
No.22, first floor, Moalem st., Abureihan St
City
Tabriz
Province
East Azarbaijan
Postal code
5154995671
Phone
+98 914 311 5717
Email
ataii.bahram@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actro Middle East Pharmaceutical Co
Full name of responsible person
Sanaz Golbabaei
Street address
No 58, 6th St, Balouchestan St, Tehran, Iran
City
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
Actro Middle East 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
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 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
These data are as secure between researchers 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
No - There is not a plan to make this available