Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Bioequivalence Study of Palbociclib 125 mg Hard Capsules of Rooyan Aqvida Compared to the Reference Drug In Iranian Healthy Volunteers

Protocol summary

Study aim

The objective of this study is to compare the rate and extent of absorption of the palbociclib-containing test product with those of the reference product and to determine the bioequivalence of the two products based on pharmacokinetic parameters. For this purpose, plasma concentrations of palbociclib will be measured in blood samples collected at predefined time points following administration of the products, and the primary pharmacokinetic parameters will be calculated and compared

Design

Bioequivalence study, crossover, double-blinded, 24 healthy volunteers. For randomization, statistical software was used.

Settings and conduct

This double-blind, crossover study will be conducted at Payesh Darou Zist-Azma. Participants will receive a single oral dose of 125 mg palbociclib (test or reference product) with food in each of two study periods separated by a 14-day washout period. Blood samples will be collected for up to 72 hours post-dose, and plasma drug concentrations will be measured using liquid chromatography. The products will be provided in visually identical, coded containers to maintain blinding.

Participants/Inclusion and exclusion criteria

Inclusion: Iranian adults aged 18–50 years of either sex. A body weight of >50 kg for males and >45 kg for females, and a body mass index (BMI) of 18.5–30 kg/m²; Exclusion: Any history of drug or food allergies, Use of any medications, Pregnancy, Breastfeeding, Underlying disease

Intervention groups

Group 1 Test product Oral administration of one 125 mg palbociclib capsule manufactured by Royan Aquiva with food, followed by measurement of plasma drug concentrations for up to 72 hours post-dose Group 2 Reference product Oral administration of one 125 mg palbociclib capsule of the reference product with food, followed by measurement of plasma drug concentrations for up to 72 hours post-dose

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261019071496N1**
Registration date: **2026-10-24, 1405/08/02**
Registration timing: **prospective**

Last update: **2026-10-24, 1405/08/02**
Update count: **0**

Registration date

2026-10-24, 1405/08/02

Registrant information

Name

Fereshteh Bayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0212

Email address

fereshtehbayat@sbmu.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-12-22, 1405/10/01

Expected recruitment end date

2027-03-21, 1406/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Bioequivalence Study of Palbociclib 125 mg Hard Capsules of Rooyan Aqvida Compared to the Reference Drug In Iranian Healthy Volunteers

Public title
Bioequivalence study of Palbociclib capsule
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian adults aged 18–50 years of either sex A body weight of >50 kg for males and >45 kg for females, and a body mass index (BMI) of 18.5–30 kg/m²
Exclusion criteria:
Any history of drug or food allergies Use of any prescription medications, over-the-counter (OTC) medications, traditional medicines, dietary supplements, or consumption of fruits such as grapefruit, mango, dragon fruit, lemon, and orange within 14 days prior to screening or during the study Pregnancy Breastfeeding Any underlying disease or clinically significant condition that, in the investigator's judgment, may affect the participant's safety, the interpretation of study results, or the metabolism and elimination of palbociclib
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **20**
Blood sample
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using statistical software.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted using a double-blind design, in which both the participants and the data analyst will be unaware of the participants' treatment allocation and the sequence in which the test and reference products are administered. To maintain blinding, the capsules of the test and reference products will be removed from their original packaging and placed in identical containers bearing unique codes. In addition, all blood samples collected during the study will be coded, and the data analyst will not have access to information regarding the participants' treatment allocation until unblinding.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of The Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences
Street address
Ethics committee of The Institute of Pharmaceutical Sciences, Tehran University of Medical Science, 16 Azar St.
City
Tehran
Province
Tehran
Postal code
1417614411
Approval date
2026-10-19, 1405/07/27
Ethics committee reference number
IR.TUMS.TIPS.REC.1405.106

Health conditions studied

1

Description of health condition studied
A crossover bioequivalence study in 24 healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration
Timepoint
Predose, 1, 2, 4, 5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10, 11, 12, 24, 36, 48, 72
Method of measurement
Liquid Chromatography with tandem mass spectrometry

Secondary outcomes

1

Description
Maximum Plasma Concentration (Cmax)
Timepoint
Predose, 1, 2, 4, 5, 6, 6.5, 7, 7.5, 8, 8.5, 9, 9.5, 10, 11, 12, 24, 36, 48, 72
Method of measurement
Liquid Chromatography with tandem mass spectrometry

2

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
After intervention
Method of measurement
Calculation of area under curve of concentration -time

Intervention groups

1

Description
Intervention group: In this group, healthy volunteers will receive one 125 mg palbociclib capsule manufactured by Royan Aquiva orally with food. Blood samples will be collected for up to 72 hours post-dose, and plasma drug concentrations will be measured. Following a 14-day washout period, participants will receive the intervention 2 product.
Category
Treatment - Drugs

2

Description
Intervention group: In this group, 12 healthy volunteers will receive a single oral dose of one 125 mg palbociclib capsule of the reference (brand-name) product with food. Blood samples will be collected for up to 72 hours post-dose, and plasma drug concentrations will be measured. Following a 14-day washout period, participants will receive the intervention 1 product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Payesh Darou Zist Azma
Full name of responsible person
Saeed Ghanbarzadeh
Street address
Imam Khomeini Street, Atlas Alley, South Imam Ali Boulevard, No. 0
City
Basmenj
Province
East Azarbaijan
Postal code
5366154042
Phone
+98 41 3383 2649
Email
payeshdarou@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rooyan Aqvida
Full name of responsible person
Seyed Ahmadreza Mirmotalebi
Street address
No. 13, Maragheh Alley, Ostad Nejatollahi St., Enghelab Ave
City
Tehran
Province
Tehran
Postal code
1599677814
Phone
+98 21 5780 3000
Email
info@rooyandarou.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rooyan Aqvida
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fereshteh Bayat
Position
Principle Investigator
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address

No 2660, School of Pharmacy, Shahid Beheshti Medical University, Valiasr Ave

City
Tehran

Province
Tehran

Postal code
1996835113

Phone
+98 21 8866 5317

Email
fereshtehbayat@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fereshteh Bayat

Position
Non-faculty specialist

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
No 2660, School of Pharmacy, Shahid Beheshti Medical University, Valiasr Ave

City
Tehran

Province
Tehran

Postal code
1996835113

Phone
+98 21 8866 5317

Email
fereshtehbayat@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Fereshteh Bayat

Position
Non-faculty specialist

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
No 2660, School of Pharmacy, Shahid Beheshti Medical University, Valiasr Ave

City
Tehran

Province
Tehran

Postal code
1996835113

Phone
+98 21 8866 5317

Email
fereshtehbayat@sbmu.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available