Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

In-vivo Bioequivalence Study of Palbociclib 125 mg capsule of The Test Drug manufactured by Cedal nano pharmacutical company in Compared with The Reference Drug IBRANCE 125 mg capsule

Protocol summary

Study aim

مسعود امانلو In-vivo Bioequivalence Study of Palbociclib 125 mg capsule of The Test Drug manufactured by Cedal nano pharmacutical company

Design

Bioequivalence study, Cross-over design, Single dose, Single-blinded, 24 healthy female volunteers, Two period, two week wash out period, Simple randomization method will be used.

Settings and conduct

This single-blind, two-period crossover study was conducted on two groups of healthy volunteers at Radin Shimi Company in Tabriz. Each period lasted 72hours, with a two-week washout interval between them. In the first period, based on computer-generated randomization, Group 1 received the reference drug while Group 2 received the test drug. In the second period, the treatments were switched. The study was single-blinded, meaning that participants were unaware whether they received the test or reference drug during either sampling period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of heart, kidney & liver disease. The ages and BMIs of participant should be in the range of 18-55 and 18-30 respectively. Exclusion criteria: Smoking, Alcohol and drug addiction, History of allergy to drug, Pregnancy.

Intervention groups

Intervention group one receivesPalbociclib 125 mg capsule of The Test Drug manufactured by Cedal nano pharmacutical company in the first round, and in the second round, after a two-week washout period, the drug IBRANCE 125 mg . Intervention group No.2 receives the drugs in the switched order.

Main outcome variables

The concentration of the drug in blood, Time to reach maximum blood concentration, Extent of absorption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240804062647N41**
Registration date: **2026-06-11, 1405/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-11, 1405/03/21**
Update count: **0**

Registration date

2026-06-11, 1405/03/21

Registrant information

Name

Massoud Amanlou

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 9067

Email address

amanlou@tums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2027-05-22, 1406/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
In-vivo Bioequivalence Study of Palbociclib 125 mg capsule of The Test Drug manufactured by Cedal nano pharmacutical company in Compared with The Reference Drug IBRANCE 125 mg capsule

Public title
In-vivo Bioequivalence Study of Palbociclib 125 mg capsule of The Test Drug manufactured by Cedal nano pharmacutical company

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General health (liver, heart, kidney) of volunteers Informed consent form Body mass index range (18-30) Age between18-55

Exclusion criteria:
Smoking Having a history of cardiovascular disease Having a history of liver & kidney disease Having a Alcohol & Drug addiction Having a hypersensitivity to the drug Pregnancy

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

Gender
Both

Phase
Bioequivalence

Groups that have been masked

- Participant

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
First, all volunteers were screened and selected according to the inclusion criteria. For random allocation, a random number for each volunteer was generated in Microsoft Excel using the RAND() function. The volunteers were then sorted based on these random numbers, and each participant was assigned a number from 1 to 24. In the first study period, participants with even numbers received the reference drug and those with odd numbers received the test drug. In the second period, the treatments were crossed over between the groups. The generation of the randomization list and the packaging of coded study medications were performed by a person independent of the evaluation team.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is designed as a single-blind clinical trial in which the participants are blinded. In this study, palbociclib 125 mg capsules of the reference brand and the test product manufactured by Cedal Nano Company are removed from their original packaging and placed into identical coded containers by an individual who is not involved in outcome assessment or data analysis. The medications are coded in such a way that the participants are unaware of the type of drug they receive (reference brand or test product). Therefore, blinding is applied at the participant level, while the investigator responsible for drug allocation has access to the coding information.

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
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street,

City
Tabriz

Province
East Azarbaijan

Postal code
5174864471

Approval date
2026-04-13, 1405/01/24

Ethics committee reference number
IR.TBZMED.REC.1405.011

Health conditions studied

1

Description of health condition studied
This study is performed on healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The concentration of the drug in blood

Timepoint
0، 1، 2، 4، 6، 8، 10، 12، 24، 48 , 72h after drug

Method of measurement
Liquid Chromatography with Mass-Mass Detector

Secondary outcomes

1

Description
Time to reach maximum blood concentration
Timepoint
After intervention
Method of measurement
The time to reach the maximum drug concentration in blood is recorded. This is done after completing the device analysis of the samples and through the WinNonLine software developed by Phoenix Company.

2

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

Intervention groups

1

Description
First intervention group: Single-dose of Palbociclib 125 mg of The Test Drug manufactured by Cedal nano pharmacutical company , in the first period.
Category
Treatment - Drugs

2

Description
Second intervention group: Single-dose of IBRANCE® 125 mg capsule in the first period.
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
Cedal Nano
Full name of responsible person
Dindust Payam
Street address
No 65, West 25 Street, Yamini Sharif Bulvar, North Amirabad, Tehran
City
Tehran
Province
Tehran
Postal code
1437713497
Phone
+98 21 8801 9794
Email
s.motahari@cedalco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cedal Nano
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
Tehran University of Medical Sciences
Full name of responsible person
Massoud Amanlou
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
16 Azar Ave., Faculty of Pharmacy
City
Tehran
Province
Tehran
Postal code
1417614411

Phone
+98 21 6695 9067
Fax
+98 21 6412 1111
Email
amanlou@tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Massoud Amanlou
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
16 Azar Ave., Faculty of Pharmacy
City
Tehran
Province
Tehran
Postal code
1417614411
Phone
+98 21 6695 9067
Fax
+98 21 6412 1111
Email
amanlou@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Massoud Amanlou
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
16 Azar Ave., Faculty of Pharmacy
City
Tehran
Province
Tehran
Postal code
1417614411
Phone
+98 21 6695 9067
Fax
+98 21 6412 1111
Email
amanlou@tums.ac.ir

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