

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

In vivo Bioequivalence study of Palbociclib 125 mg capsule manufactured by Sobhan Oncology Pharmaceutical Co. Compared to innovator Product

Protocol summary

Study aim

In vivo fasted-state bioequivalence study of Palbociclib 125 mg capsule

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. 24 healthy male volunteers will participate randomly in the study as two twelve-person groups. Each volunteer will receive a single dose in two periods. In one period the test and in another period the reference formulation. Therefore, each volunteer will be his own "Control". To randomly assign participants in two groups, the lottery method will be used.

Settings and conduct

After oral administration of one 125 mg capsule to volunteer, the blood samples will be collected in predetermined time intervals up to 72 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. The concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. The study will be performed in Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney diseases), Age (18-59 years old) Exclusion criteria: Smoking, History of cardiovascular disease, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy

Intervention groups

Intervention group will receive a single oral dose of test drug product (Palbociclib 125 mg capsule manufactured by Sobhan Oncology, Iran) and Control group will receive a single dose of reference drug product (Palbociclib 125 mg capsule manufactured by Fizer). Blood samples will be taken from the volunteers for 72 hours at the mentioned time points after drug administration and the plasma will be stored in freezer until analysis. In both groups, breakfast and lunch will be served two and six

hours after drug administration, respectively).

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220211053992N19**

Registration date: **2023-12-25, 1402/10/04**

Registration timing: **prospective**

Last update: **2023-12-25, 1402/10/04**

Update count: **0**

Registration date

2023-12-25, 1402/10/04

Registrant information

Name

Hadi Valizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8801

Email address

valizadehh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-12-20, 1403/09/30

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 manufactured by Sobhan Oncology Pharmaceutical Co. Compared to innovator Product

Public title
In vivo Bioequivalence study of Palbociclib capsule

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
General Health (in terms of Liver, Heart and Kidney diseases) Age between 18 to 59 years
Exclusion criteria:
Smoking History of cardiovascular, liver, and kidney disease Pregnancy Alcohol and drug addiction History of drug allergy

Age
From **18 years** old to **59 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.

Blinding (investigator's opinion)
Not blinded

Blinding description

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
No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Approval date
2023-12-18, 1402/09/27

Ethics committee reference number
IR.TBZMED.REC.1402.698

Health conditions studied

1

Description of health condition studied

In the present study, the products will be administered to healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration of drug

Timepoint

0.5-72 hours in predetermined time intervals after drug administration

Method of measurement

HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group will receive a single oral dose of test product (Palbociclib 125 mg capsule manufactured by Sobhan Oncology Co., Iran) in fasted state. Blood samples will be collected for 272 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.

Category

Treatment - Drugs

2

Description

Control group: Control group will receive a single oral

dose of reference product (Palbociclib 125 mg capsule manufactured by Fizer) in fasted state. Blood samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Pharmacy, Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori St., Golgash St.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Fax**Email**

valizadehh@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

No.2 Central Building, 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Fax**Email**

shahabip@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Sobhan Oncology Company

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**

Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Email

valizadehh@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Email
valizadehh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Hadi Valizadeh
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Street address
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East Azarbaijan

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable