Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

In- Vivo Bioequivalence study of Lenalidomide cap. 25mg Sobhan Oncology (LENASOB® 25mg) with brand drug (REVLIMID® 25mg Colgene, Bristol-Myers Squibb) in Iranian healthy volunteers

Protocol summary

Study aim

In- Vivo Bioequivalence study of Lenalidomide cap. 25mg Sobhan Oncology Pharma with brand drug (REVLIMID® 25mg,Colgene, Bristol-Myers Squibb) in Iranian healthy volunteers.

Design

Single dose, randomized, two sequences, two period crossover with a washout period.

Settings and conduct

This study will be conducted in one-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours.The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form.In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis functions with both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-28 respectively

Intervention groups

Intervention group Single dose Lenalidomide cap. 25mg Sobhan Oncology Pharma Company with brand drugs (REVLIMID® 25mg, Colgene, Bristol-Myers Squibb)

Main outcome variables

Determination of blood drug concentration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N26**
Registration date: **2021-03-12, 1399/12/22**
Registration timing: **prospective**

Last update: **2021-03-12, 1399/12/22**
Update count: **0**

Registration date

2021-03-12, 1399/12/22

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

2021-03-15, 1399/12/25

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
In- Vivo Bioequivalence study of Lenalidomide cap. 25mg Sobhan Oncology (LENASOB® 25mg) with brand drug (REVLIMID® 25mg Colgene, Bristol-Myers Squibb) in Iranian healthy volunteers

Public title
Lenalidomide cap. 25mg Sobhan Oncology (LENASOB® 25mg), In-Vivo Bioequivalence in iranian healthy volunteer.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
General health(liver, heart, kidney) Body mass index(18-28) Informed consent Age(18-60)
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
People in different age groups are invited to cooperate through the advertisement.Then people are selected. Individuals will be randomly selected through advertisements. The number of individuals will be randomly selected and the first twelve will be selected as the first sequence and the second twelve will be selected as the second sequence.

Blinding (investigator's opinion)
Single blinded

Blinding description
Candidates are not aware of the test drug or brand name.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Tabriz University of Medical Sciences
Street address
Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766

Approval date
2021-03-01, 1399/12/11

Ethics committee reference number
IR.TBZMED.REC.1399.1114

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. Subject bioequivalence test and reference tablets Teriflunomide studied.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determination of blood drug concentration.

Timepoint
Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours After prescribing the tablet.

Method of measurement
igh Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group received one test drug table(Lenalidomide cap. 25mg Sobhan Oncology Pharma). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of LENASOB in blood samples was measured by liquid chromatography with mass spectroscopy detector.

Category

Treatment - Drugs

2

Description
Control group: Control group received one test drug cap. (REVLIMID® 25 mg Colgene, Bristol-Myers Squibb). Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of REVLIMID in blood samples was measured by liquid chromatography with mass spectroscopy detector.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Simin Baspar Teyf Gostar Company
Full name of responsible person
Javad Shokri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
SOBHAN ONCOLOGY Pharmaceutical
Full name of responsible person
Majid Anabi
Street address
Tehran - Shahid Beheshti St. Ahmad Qasir St. 5th St. No. 11
City
Tehran
Province
Tehran
Postal code
1654613111
Phone
+98 21 8848 0161
Email
info@bpharmed.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz University of Medical Sciences
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
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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 date are as secure between researcher 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
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
Only protocol and methods of study are sharable.
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
This information is confidential and is at the disposal of the project sponsor. Upon request, the information will be provided to the applicant by the contractor's email after the
Comments