Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

In- Vivo Bioequivalence study of Lenalidomide tablet 25mg ABIDI (MYLODEQ® 25mg) with brand drug (REVLIMID® 25mg Colgene, Bristol-Myers Squibb) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Lenalidomide tablet 25 mg ABIDI (MYLODEQ® 25 mg) with brand drug (REVLIMID® 25 mg Colgene, Bristol-Myers Squibb)

Design

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

Settings and conduct

This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four 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 18-25 respectively.

Intervention groups

After prescribing a single dose of the drug from the test sample and reference to the volunteers at specified times, serum samples were taken and by liquid extraction method and using derivation method by device with HPLC, LC-MS / MS or UPLC-MS The amount of drug is determined.

Main outcome variables

Cmax,Tmax, T1/2, Ke (Elemination)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N6**
Registration date: **2020-07-21, 1399/04/31**
Registration timing: **prospective**

Last update: **2020-07-21, 1399/04/31**
Update count: **0**

Registration date

2020-07-21, 1399/04/31

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

2020-10-25, 1399/08/04

Expected recruitment end date

2021-05-25, 1400/03/04

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

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

Public title
Lenalidomide tablet 25mg ABIDI (MYLODEQ® 25mg), In-Vivo Bioequivalence in iranian healthy volunteer, 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
No information
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
Tow period / Tow sequence with a washout time

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences Ethics Committee
Street address
No.48,Ferdows Street, Ferdowsi Sq.
City
Tabriz
Province
East Azarbaijan
Postal code
51678744
Approval date
2020-06-22, 1399/04/02
Ethics committee reference number
IR.TBZMED.REC.1399.315

Health conditions studied

1

Description of health condition studied
In this study the bioequivalence of test and brand of Lenalidomide tablet will evaluated.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug analysis in plasma or whole blood
Timepoint
After blood sampling
Method of measurement
HPLC,LC-MS/MS or UPLC-MS/MS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Single dose of Lenalidomide 25 mg table by (REVLIMID® 25 mg Colgene, Bristol-Myers Squibb)
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: Single dose of Lenalidomide tablet 25 mg ABIDI (MYLODEQ® 25mg)

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
Tabriz University of Medical Sciences
Full name of responsible person
Amir Razavian
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Tehran, 8 km of Shahid Lashkari Highway Abidi Boulevard No. 72
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Tehran
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Fax
+98 21 4450 4787
Email
info@abidi-diabetes.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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
Industry

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
After finishing of the protocol (Probably 6 months receiving IRCT code)

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
Contact with E-mail of the main researcher.

What processes are involved for a request to access data/document
Personal and academic details and the aim of the request.

Comments