Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

In- Vivo Bioequivalence study of Linalidomide capsule 25 mg (Actero Pharma., Iran) with brand drug (REVLIMID® 25 mg, Celgene, Bristol-Myers Squibb,UK) in Iranian healthy volunteers.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Linalidomide capsule 25 mg Actero Pharma. with brand drug (REVLIMID® 25 mg, Celgene, Bristol-Myers Squibb,UK) in Iranian healthy volunteers.

Design

In-vivo bioequivalence study of Linalidomide 25 mg hard gelatin capsules (Actero Middle East, Iran) with reference drug (REVLIMID® 25 mg, Celgene, Bristol-Myers Squibb, UK). The single blind, Cross-over, two period, two sequences (Intervention and control) and randomized study with one week wash-out period.

Settings and conduct

study background is biopharmacy and pharmcokinetics. Place of study is Simin Baspar Tayf-Gostar Inc, Tabriz. Study blinding will done by taking the test and reference drugs out of their original packaging and put them in the similar packaging. The volunteers will not be informed about the type of received drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-55 years, body mass index (BMI) in the range of 18-28. Exclusion criteria: History of heart, kidney and liver disease, Pregnancy, Drug addiction, Smoking

Intervention groups

Intervention group: Single dose of Linalidomide capsules 25 mg Actro Pharma. Control group: Single dose of brand drugs (REVLIMID® 25 mg, Celgene, Bristol-Myers Squibb, UK). The study is designed as cross-over in two 72-hours period with one week wash out time. The interfering factors in the study including: inter-subject variability of volunteers, type of drug and healthy condition of volunteers.

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N53**
Registration date: **2022-01-23, 1400/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-23, 1400/11/03**
Update count: **0**

Registration date

2022-01-23, 1400/11/03

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

2021-12-01, 1400/09/10

Expected recruitment end date

2022-07-01, 1401/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
In- Vivo Bioequivalence study of Linalidomide capsule 25 mg (Actero Pharma., Iran) with brand drug (REVLIMID® 25 mg, Celgene, Bristol-Myers Squibb,UK) in Iranian healthy volunteers.

Public title
In-vivo Bioequivalence Test of Linalidomide capsules with brand drug (REVLIMID® 25 mg, Celgene, Bristol-Myers Squibb, UK)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
General health Body mass index between18-28 Informed consent Being at the age of 18-55 years old

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 **55 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
For this purpose, A 24- persons group will be selected and divided to two 12-persons groups randomly. The names of all volunteers will be written on paper pieces and wrapped in aluminum foils. The first 12 papers will randomly be withdrawn from bottle will be selected as group A and others will be categorized in group B.

Blinding (investigator's opinion)
Single blinded

Blinding description
Information of the type of administered drugs will be kept hidden from volunteers. Test and Brand drugs are removed from their packaging by the executor and placed in similar cans. Volunteers will not be informed about receiving the brand or test drug.

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
Third floor; Central building; Tabriz University of Medical Sciences; Dneshgah St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2021-11-15, 1400/08/24

Ethics committee reference number
IR.TBZMED.REC.1400.732

Health conditions studied

1

Description of health condition studied
Bio equivalence test

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plasma 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 taking the tablet.

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

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One test capsule (Lenalidomide tablet 25 mg, Actro Pharma.) will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and concentrations of the drug in Plasma samples will be measured by liquid chromatography with mass spectroscopy detector. The study is designed as cross-over, two 72-hours period with one week wash out time. The interfering factors in the study including: inter-subject variability of volunteers, type of drug and healthy condition of volunteers.

Category
Treatment - Other

2

Description
Control group: One Reference capsule (REVLIMID® 25 mg, Celgene, Bristol-Myers Squibb, UK) will be received. Blood samples will be taken for 72 hours at the mentioned times after drug administration and the concentration of Lenalidomide in plasma samples will be measured by liquid chromatography with mass spectroscopy detector. The study is designed as cross-over, two 72-hours period with one week wash out time. The interfering factors in the study including: inter-subject variability of volunteers, type of drug and healthy condition of volunteers.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Simin Baspar Teyf Gostar Company

Full name of responsible person
Javad Shokri

Street address
No.48, Ferdos square

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Tabriz

Province
East Azarbaijan

Postal code
5167874434

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+98 41 3384 2724

Email
Shokri.j@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Actero middle east Pharm. Co.

Full name of responsible person
Sanaz Golbabaei

Street address
Tehran

City
No 58, 6th St, Balouchestan St, Tehran, Iran

Province
Tehran

Postal code
1446863914

Phone
+98 21 4431 9003

Email
info@actoverco.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Actero middle east Pharm. Co.

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

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Faculty of Pharmacy, Tabriz University of Medical Sciences, Daneshgah

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Shokri.j@gmail.com

Person responsible for scientific inquiries

Contact

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Full name of responsible person
Javad Shokri

Position
Professor

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Person responsible for updating data

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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
All information and data of the study will remain secured based on the agreement established between researcher and drug producer.

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
The access to data will be possible after finishing of project (almost 6 months after receiving of 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
By email to the project manager (shokri.j@gmail.com)

What processes are involved for a request to access data/document
These information are confidential and be under disposal of the project's contractor. Upon request, the information will be accessed to the applicant by the Executor's email after receiving contractor's consent.

Comments