

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 pharmacokinetics. 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 Actero 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 between 18-28 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 centers1**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

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5167874434

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+98 41 3384 2724

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Shokri.j@gmail.com

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Actero middle east Pharm. Co.

Full name of responsible person

Sanaz Golbabaie

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

Tabriz University of Medical Sciences

Full name of responsible person

Javad Shokri

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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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