Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Bioequivalence study of the Valacyclovir 500 mg tablets manufactured Iran hormone pharmaceutical Co.

Protocol summary

Study aim

Demonstration of bioequivalence of Valaciclovir 500-mg tablet of Iran hormone with Valtrex ® tablet manufactured by GlaxoSmithKline after single dose administration.

Design

A single-group, not blinded, not randomized, bioequivalence clinical trial on 24 healthy volunteers.

Settings and conduct

Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. The number of 24 volunteer in the age range of 18-50years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken at 16 times point. One week later, the process is repeated for the brand medicine

Participants/Inclusion and exclusion criteria

The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form

Intervention groups

After taking a Valaciclovir 500-mg tablet from domestic company, 3 milliliters of blood will be collected from the volunteer in 16 times intervals for 12 hours. One week later, the process is repeated for a brand sample tablet. The drug concentration is measured in plasma

Main outcome variables

Studying the Drug pharmacokinetic parameters including measuring the plasma concentrations for brand and test products, determining the desired and important pharmacokinetic parameters in bioequivalence studies, AUCs, Tmax, Cmax, T1/2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130313012810N40**
Registration date: **2024-10-24, 1403/08/03**
Registration timing: **prospective**

Last update: **2024-10-24, 1403/08/03**
Update count: **0**

Registration date

2024-10-24, 1403/08/03

Registrant information

Name

Hamed Hamishehkar

Name of organization / entity

Drug Applied Research Center, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-30, 1403/08/09

Expected recruitment end date

2024-11-01, 1403/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of the Valacyclovir 500 mg tablets manufactured Iran hormone pharmaceutical Co.

Public title

Valaciclovir tablet bioequivalence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The weight range of participating candidates should be between 60-100 kg Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose. Volunteers who have agreed to an informed consent form. All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw

Exclusion criteria:

History of allergic or adverse reaction to Valaciclovir or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Individuals who donated whole blood or blood components within 2 months within 2 weeks prior to the first dose of the study product(s) Smokers

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

N/A

Randomization description

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

Drug Applied Research Center, Tabriz University of Medical Sciences Daneshgah St.

City

Tabriz

Province

East Azarbaijan

Postal code

51656-65811

Approval date

2024-10-14, 1403/07/23

Ethics committee reference number

IR.TBZMED.REC.1403.586

Health conditions studied

1

Description of health condition studied

Bioequivalence study in healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration of the drug

Timepoint

16 sampling time till 12 h

Method of measurement

En Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1, which consists of 24 healthy and fasting volunteers, will receive a tablet with a dose of 500 mg manufactured by Iran hormone Pharmaceutical Company.

Category

N/A

2

Description
Intervention group 2, which consists of 24 healthy and fasting volunteers, will receive a Valtrex® tablet with a dose of 500 mg manufactured by GlaxoSmithKline Pharmaceutical Company.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran hormone
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran hormone
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
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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

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

No - There is not a plan to make this available