

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 ( $\gamma$ -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, T<sub>max</sub>, C<sub>max</sub>, T<sub>1/2</sub>

#### 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

+98 41 1336 3311

##### Email address

hamishehkar.hamed@gmail.com

##### 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

Hamed Hamishehkar

##### Street address

Daneshgah st

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

51656-65811

##### Phone

+98 41 3336 3311

##### Email

hamishehkar.hamed@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran hormone

##### Full name of responsible person

Mehdi Amani

##### Street address

Km 11 Karaj Makhsous Road

##### City

Tehran

##### Province

Tehran

##### Postal code

1399813611

##### Phone

+98 21 4490 5517

##### Email

info@iranhormone.com

#### 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

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Mehrdad Hamidi

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Zanjan University of Medical Sciences, Sobooti road, Zanjan, Zanjan Province

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956184

##### Phone

+98 24 3342 0651

##### Email

hamidi@hidapharma.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Mehrdad Hamidi

##### Position

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

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**Email**

hamidi@hidapharma.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

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Hamed Hamishehkar

**Position**

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**Postal code**

51656-65811

**Phone**

+98 41 3336 3181

**Fax**

**Email**

hamishehkar.hamed@gmail.com

**Web page address**

**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