Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Bioequivalence study of valacyclovir 1000 mg tablet (Avicenna) versus VALTREX ® 1000 mg (GlaxoSmithKline) Tablet in healthy volunteers

Protocol summary

Study aim

Bioequivalence study of valacyclovir 1000 mg tablet (Avicenna) versus VALTREX ® 1000 mg (GlaxoSmithKline) Tablet in healthy volunteers

Design

Bioequivalence study, with control group, double-blind, randomized, on 24 volunteers, from each volunteer 17 blood samples were taken. Excel software rand function is used for randomization.

Settings and conduct

The subject of this biopharmaceutical and pharmacokinetic study is the location of Tehran Shimi Company located in Tehran. The study was blinded to the study participants by removing the drugs from the original package and placing the test and reference drugs in the same package, and the participants were not aware of the type of drug they were taking. The crossover design is such that Iranian medicine will be prescribed to the first group in the first week and to the second group in the second week. Brand medicine will be prescribed to the second group in the first week and to the first group in the second week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: general health (liver, heart and kidneys), body mass index (18-28), informed consent, age (55-18) Exclusion criteria: smoking, history of cardiovascular disease, history of liver disease and Renal, alcohol and drug addiction, history of allergy to valaciclovir

Intervention groups

Determination of blood concentration profile parity of brand drug with generics

Main outcome variables

Comparison of bioequivalence of two products based on the criteria of the Food and Drug Administration of Iran and the FDA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220111053692N1**
Registration date: **2022-05-18, 1401/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-18, 1401/02/28**
Update count: **0**

Registration date

2022-05-18, 1401/02/28

Registrant information

Name

Bardia Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 4707

Email address

info@tampouya.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-06-13, 1401/03/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of valacyclovir 1000 mg tablet (Avicenna) versus VALTREX ® 1000 mg (GlaxoSmithKline) Tablet in healthy volunteers

Public title

Bioequivalence study of valacyclovir 1000 mg tablet (Avicenna) versus VALTREX ® 1000 mg (GlaxoSmithKline) Tablet in healthy volunteers

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 55 years old Weight in range of 10 % proper body weight All volunteers should be in a good health condition on the basis of medical history ,physical examination , routine blood test. and possessing negative test for hepatitis B surface antigen (HBs-Ag),antihepatitis-C antibody (anti-HCV).and anti-HIV. just man

Exclusion criteria:

Volunteers with hypersensitivity to valacyclovir were excluded. those with known history of drug abuse. alcohol consumer or cigarette smokers. Taking medications that have drug interactions with valacyclovir until one month before studying. disinclination Blood donation or blood loss of more than 200 ml in the past month

Age

From **18 years** old to **55 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **17**

5 cc per turn

Randomization (investigator's opinion)

Randomized

Randomization description

Using Excel software in a balanced way, one of the AB or BA sequences is randomly assigned to each candidate.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a Double-blind (participant) clinical trial. Valacyclovir and valterex tablets are removed from the package by the administrator and placed in similar and coded cans.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of The Institute of Pharmaceutical Sciences -Tehran University of Medical

Street address

Research Institute of Pharmaceutical Sciences, second floor of the old building, Faculty of Pharmacy, Enqelab Square, 16 Azar St.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-10-31, 1400/08/09

Ethics committee reference number

IR.TUMS.TIPS.REC.1400.165

Health conditions studied

1

Description of health condition studied

Bioequivalence study of valacyclovir 1000 mg tablet (Avicenna) versus VALTREX ® 1000 mg (GlaxoSmithKline) Tablet after single oral dosing in healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination of blood concentration

Timepoint

0,0/25,0/5,0/75,1,1/25,1/5,1/75,2,2/5,3,4,6,8,10,24,30

Method of measurement

HPLC-UV

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receives one tablet of test drug (valaciclovir 1000 mg from Oh Sina Pharmaceutical

Company). Blood samples were taken from the volunteers for 24 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector.

Category

Treatment - Other

2

Description

Control group: Receives one reference medicine tablet (Valtrex 1000 mg from GlaxoSmithKline). Blood samples were taken from the volunteers for 24 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Chemie Pharmaceuticals Co

Full name of responsible person

Bardia jamali

Street address

Navard Ave,5th Km Fat`h Highway

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Avicenna pharmaceutical Co.

Full name of responsible person

Dr. Siamak Mirtorabi

Street address

No. 8, No. 23, Jahan Ara St., Yousef Abad St.

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1438933741

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Email

export@avicenna.ir

Web page address

http://www.avicenna.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Avicenna pharmaceutical 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tam Pouya Consulting & Research Company

Full name of responsible person

Bardia jamali

Position

manager

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

Tam Pouya Consulting & Research Company

Full name of responsible person

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Position
manager

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
Tam Pouya Consulting & Research Company

Full name of responsible person
Motahareh moafi

Position
Office worker

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Bachelor

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Office worker

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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
No more information

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