

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

In vivo bioequivalence study of Valsartan 80 mg tablet of Pursina pharmaceutical Co. compared to innovator product

Protocol summary

Study aim

In vivo fasted-state bioequivalence study of Valsartan tablet

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy volunteers will participate randomly in the study as two twelve-person study groups. To randomly assign participants in two groups, the lottery method will be used.

Settings and conduct

After oral administration of one Valsartan 80 mg tablet, the blood samples will be collected in predetermined time intervals up to 32 hours. The samples will be stored in freezer -4 degrees centigrade until analysis. The concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences. This study will be conducted without blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old) Exclusion criteria: Smoking, History of cardiovascular, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy

Intervention groups

Intervention group will receive a single oral dose of test product (Valsartan tablet of Pursina Co.) and Control group will receive a single dose of reference product (Valsartan tablet of Novartis Co.). Blood samples will be taken for 32 hours at the mentioned time points and the plasma will be stored in freezer until analysis. In both groups, breakfast and lunch will be served two and six hours after drug administration, respectively.

Main outcome variables

Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220211053992N15**

Registration date: **2023-09-27, 1402/07/05**

Registration timing: **prospective**

Last update: **2023-09-27, 1402/07/05**

Update count: **0**

Registration date

2023-09-27, 1402/07/05

Registrant information

Name

Hadi Valizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8801

Email address

valizadehh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-12, 1402/07/20

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo bioequivalence study of Valsartan 80 mg tablet of Pursina pharmaceutical Co. compared to innovator product	
Public title	Tabriz
Purpose	Province
Investigating bioequivalence of valsartan tablet	East Azarbaijan
Other	Postal code
	51664-14766
Inclusion/Exclusion criteria	Approval date
Inclusion criteria:	2023-09-25, 1402/07/03
General Health (in terms of Liver, Heart and Kidney) Age (18-59 years old)	Ethics committee reference number
Exclusion criteria:	IR.TBZMED.REC.1402.462
Smoking History of cardiovascular, liver and kidney disease Pregnancy Alcohol and drug addiction History of drug allergy	
Age	Health conditions studied
From 18 years old to 59 years old	<u>1</u>
Gender	Description of health condition studied
Both	In the present study, the products will be administered to healthy volunteers.
	ICD-10 code
	ICD-10 code description
Phase	
Bioequivalence	
Groups that have been masked	Primary outcomes
No information	<u>1</u>
Sample size	Description
Target sample size: 24	Plasma concentration of drug
Randomization (investigator's opinion)	Timepoint
Randomized	0.5-32 hours in predetermined time intervals after drug administration
Randomization description	Method of measurement
To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.	HPLC (High performance liquid chromatography)
Blinding (investigator's opinion)	Secondary outcomes
Not blinded	empty
Blinding description	Intervention groups
Placebo	<u>1</u>
Not used	Description
Assignment	Intervention group: Intervention group will receive a single oral dose of test product (Valsartan 80 mg tablet manufactured by Pursina Co.) in fasted state. Blood samples will be collected for 32 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.
Other design features	Category
	Treatment - Drugs
Secondary Ids	<u>2</u>
empty	Description
Ethics committees	Control group: Control group will receive a single oral dose of reference product (Valsartan 80 mg tablet manufactured by Novartis) in fasted state. Blood samples will be collected for 32 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours
<u>1</u>	
Ethics committee	
Name of ethics committee	
Ethics Committee of Tabriz University of Medical Sciences	
Street address	
No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.	
City	

after drug administration, respectively.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Pharmacy, Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori St., Golgash St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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No.2 Central Building, 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.

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shahabip@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Pursina 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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hadi Valizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable