

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

In vivo fasted-state bioequivalence study of Primidone 125 mg/5ml suspension manufactured by Ashbal shimi Pharmaceutical Co. compared to innovator product

Protocol summary

Study aim

In vivo fasted-state bioequivalence study of Primidone suspension

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. 24 healthy male volunteers will participate randomly in the study as two twelve-person groups. Each volunteer will receive a single dose in two periods. In one period the test and in another period the reference formulation. Therefore, each volunteer will be his own "Control". To randomly assign participants in two groups, the lottery method will be used.

Settings and conduct

After oral administration of 2.5 ml Primidone suspension to volunteer, the blood samples will be collected in predetermined time intervals up to 72 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. 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.

Participants/Inclusion and exclusion criteria

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

Intervention groups

Intervention group will receive a 2.5 ml of test drug product (Primidone suspension manufactured by Ashbal Shimi, Iran) and Control group will receive 2.5 ml of reference drug product (Primidone suspension manufactured in Germany). Blood samples will be taken from the volunteers for 72 hours at the mentioned time points after drug administration 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: **IRCT20220211053992N17**

Registration date: **2023-12-23, 1402/10/02**

Registration timing: **prospective**

Last update: **2023-12-23, 1402/10/02**

Update count: **0**

Registration date

2023-12-23, 1402/10/02

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

2024-01-10, 1402/10/20

Expected recruitment end date

2024-11-20, 1403/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo fasted-state bioequivalence study of Primidone 125 mg/5ml suspension manufactured by Ashbal shimi Pharmaceutical Co. compared to innovator product

Public title

In vivo Bioequivalence study of Primidone suspension

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

General Health (in terms of Liver, Heart and Kidney diseases) Age between 18 to 59 years

Exclusion criteria:

Smoking History of cardiovascular, liver, and kidney disease Pregnancy Alcohol and drug addiction History of drug allergy

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

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.

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

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

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2023-12-18, 1402/09/27

Ethics committee reference number

IR.TBZMED.REC.1402.690

Health conditions studied**1****Description of health condition studied**

In the present study, the products will be administered to healthy volunteers.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plasma concentration of drug

Timepoint

0.5-72 hours in predetermined time intervals after drug administration

Method of measurement

HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group will receive 2.5 ml of test product (Primidone suspension of Ashbal Shimi, Iran) in fasted state. Blood samples will be collected for 72 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.

Category

Treatment - Drugs

2

Description

Control group: Control group will receive 2.5 ml of reference product (Primidone suspension manufactured Germany) in fasted state. Blood samples will be collected for 72 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.

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.

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Fax

Email

valizadehh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Fax

Email

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

Ashbal Shimi Company

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

Street address

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

City

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Province

East Azarbaijan

Postal code

51664-14766

Phone

+98 41 3334 8801

Email

valizadehh@gmail.com

Person responsible for scientific 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

Street address

Faculty of Pharmacy, Tabriz University of Medical

Sciences, Attar Neishaboori st., Golgasht st.

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Person responsible for updating data

Contact

Name of organization / entity

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City

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

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

Analytic Code

Not applicable

Data Dictionary

Not applicable