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

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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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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

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

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Person responsible for scientific inquiries

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Position
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable