Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

In vivo Fasted state Bioequivalence study of peptilock chewable tablet in comparison to innovator product

Protocol summary

Study aim
Investigating in vivo bioequivalence study of Ursodeoxy cholic acid chewable tablet

Design
Twenty-four healthy male volunteer will enter the study based on random numbers table as two groups of twelve people. Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation (without knowing the formulation identity in each period). Therefore, each volunteer will be his own "Control".

Settings and conduct
After administration of one chewable tablet to volunteer, the blood samples will be taken in predetermined time intervals up to 12 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. In this study the volunteer would not be aware of the formulation identity in each period

Participants/Inclusion and exclusion criteria
Inclusion criteria: General Health (Liver, Heart and Kidney), Age (18-60) 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 one test drug product. Blood samples will be taken from the volunteers for 12 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector. Control group: Control group will receive one reference drug product. Blood samples will be taken from the volunteers for 12 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Main outcome variables
Drug plasma concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210519051345N8**
Registration date: **2021-12-31, 1400/10/10**
Registration timing: **prospective**

Last update: **2021-12-31, 1400/10/10**
Update count: **0**

Registration date
2021-12-31, 1400/10/10

Registrant information

Name
Parvin Zakeri-Milani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 8801

Email address
pzakeri@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-05, 1400/10/15

Expected recruitment end date
2022-01-20, 1400/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

In vivo Fasted state Bioequivalence study of peptilock chewable tablet in comparison to innovator product

Public title
In vivo Bioequivalence study of peptilock chewable tablet
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
General Health (Liver, Heart and Kidney),
Exclusion criteria:
Smoking, History of cardiovascular disease, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
A table of random numbers will be used. First, a two-digit code (according to the number of volunteers, which is 24) is given to each candidate, and after creating the table, a random selection of numbers is made. To select sample people from the table, randomly start from a point in the table moving in the direction of the row or column. The selection of the point can be done by closing the eyes and placing a finger or the tip of a pen on the table. Moving in the direction of the row or column does not make any difference and this is optional. After this, the path numbers are controlled, which will be dealt with two types of numbers, one of which is smaller than the volume of the population of the study and the other is larger than the number of the population. Only smaller numbers should be considered and selected. The selected number is actually the individual code that is selected as the sample. This should be continued until enough small number can be selected based on the number of volunteers. The selected individuals are placed in groups one and two. The lottery method is used to assign test drug or reference drug to groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, Volunteers participating will be blinded to the type of product they are taking in each period (test or reference product). This means that the product will be given to the volunteers for administration outside the original packaging
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Biomedical Research Committe, Tabriz University of Medical Sciences
Street address
کمیته اخلاق در پژوهشهای بیومدیکال دانشگاه علوم پزشکی تبریز
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Approval date
2021-12-18, 1400/09/27
Ethics committee reference number
927.IR.TBZMED.REC.1400

Health conditions studied

1

Description of health condition studied
In the present study, no diseases will be examined and products will be administered by healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma Drug Concentration
Timepoint
0.5-12 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 one test drug product. Blood samples will be taken from the volunteers for 12 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector.

Category
Treatment - Drugs

2

Description
Control group: Control group will receive one reference drug product. Blood samples will be taken from the volunteers for12 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector.
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
Parvin Zakeri-Milani
Street address
Faculty of Pharmacy, Golgasht st Attar Neishaboori st. Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Phone
+98 41 3334 8801
Email
pzakeri@tbzmed.ac.ir

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, Daneshgah st. Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Phone
+98 41 3334 8801
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
Alhavi 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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parvin Zakeri-Milani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Golgasht st Attar Neishaboori st. Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Phone
+98 41 3334 8801
Email
pzakeri@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parvin Zakeri-Milani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Golgasht st Attar Neishaboori st. Tabriz University of Medical Sciences

City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Phone
+98 41 3334 8801
Email
pzakeri@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parvin Zakeri-Milani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Golgasht st Attar Neishaboori st. Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Phone
+98 41 3334 8801
Email
pzakeri@tbzmed.ac.ir

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