Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence study of Ursodeoxycholic acid 300mg capsule manufactured by Osveh Co. compared with innovator product

Protocol summary

Study aim

In vivo fasted-state bioequivalence study of Ursodeoxy cholic acid 300 mg capsule

Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy male volunteers will participate randomly in the study as two twelve-person study groups. 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. 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 one 300-mg capsule, 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. 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 (Ursodeoxy cholic acid 300 mg capsule of Osveh) and Control group will receive a single dose of reference product (Ursodeoxy cholic acid 300 mg capsule of STEDI Co., Spain). Blood samples will be taken for 72 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: **IRCT20210519051345N19**
Registration date: **2022-11-04, 1401/08/13**
Registration timing: **prospective**

Last update: **2022-11-04, 1401/08/13**
Update count: **0**

Registration date

2022-11-04, 1401/08/13

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

2022-12-06, 1401/09/15

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Ursodeoxycholic acid 300mg capsule manufactured by Osveh Co. compared with innovator product

Public title

Investigating the in vivo bioequivalence of Ursodeoxycholic acid 300 mg capsule

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

General Health (in terms of 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 **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

Biomedical Research Committe, Tabriz University of Medical Sciences

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

51664-14766

Approval date

2022-10-31, 1401/08/09

Ethics committee reference number

IR.TBZMED.REC.1401.703

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: Intervention group will receive a single oral dose of test product (Ursodeoxy cholic acid 300 mg capsule manufactured by Osveh Co.) 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 a single oral

dose of reference product (Ursodeoxy cholic acid 300 mg capsule manufactured by STEDI Co., Spain) 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

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

Street address

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

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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

Street address

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

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Grant name

Grant code / Reference number

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

No

Title of funding source

Osveh Pharmaceutical 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

Parvin Zakeri-Milani

Position

Professor

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

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

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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
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