

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Bioequivalence study of Ursodeoxycholic acid 300mg capsule manufactured by Pars Behrouzan Jam Co. compared with innovator product

#### Protocol summary

##### Study aim

In vivo fasted-state bioequivalence study of Ursodeoxycholic acid 300 500 mg capsule

##### Design

Twenty-four healthy male volunteers will participate 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".

##### Settings and conduct

After oral administration of one 300-mg capsule 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), 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 drug product (Ursodeoxy cholic acid 300 mg capsule manufactured by Pars Behrouzan Jam) and Control group will receive a single dose of reference drug product (Urso deoxy cholic acid 300 mg capsule manufactured by STEDI Co., Spain). 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: **IRCT20210519051345N16**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

##### Registration date

2022-09-03, 1401/06/12

##### 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

2022-10-02, 1401/07/10

##### Expected recruitment end date

2023-03-30, 1402/01/10

##### 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 Pars Behrouzan Jam 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 Committee, Tabriz University of Medical Sciences

**Street address**

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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

51664-14766

**Approval date**

2022-08-01, 1401/05/10

**Ethics committee reference number**

IR.TBZMED.REC.1401.401

**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 a single oral dose of test product (Ursodeoxy cholic acid 300 mg capsule manufactured by Pars Behrouzan Jam 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**

Faculty of Pharmacy, Tabriz University of Medical Sciences

**Full name of responsible person**

Parvin Zakeri-Milani

**Street address**

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

**City**

Tabriz

**Province**

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**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, University of Medical Sciences, Daneshgah st.

**City**

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**Province**

East Azarbaijan

**Postal code**

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**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**

Pars Behrouzan Jam 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

**Street address**

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

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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Professor

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## 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, University of Medical Sciences,  
Golgasht st., Attar Neishaboori st.  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**

## 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