

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Bioequivalence study of 300 mg ursodeoxycholic acid capsule of Kimidaro Pharmaceutical Company compared to 300 mg ursodeoxycholic acid of Aurobindo Pharma LTD, India on healthy volunteers

#### Protocol summary

##### Study aim

Comparison of absorption of two ursodeoxycholic acid capsules

##### Design

The present clinical trial includes the bioequivalence study of ursodeoxycholic acid capsule 300 mg manufactured by Kimidarou Pharmaceutical Company of Iran compared to the same sample manufactured by Aurobindo Pharma LTD of India, after administration to 24 healthy human volunteers, in two intervention groups. It is cross-over, unblinded and non-randomized.

##### Settings and conduct

The study is carried out at Nik Azma Pars Alborz Company located in No. 419, Azadegan Square, Imam Khomeini Blvd., Mahdasht Karaj. A cross-over unblinded study, consisting of two phases (oral administration of two 300 mg ursodeoxycholic acid capsules per study and 2 times in total) with a four-week washout period on 24 healthy volunteers are fasting. 5 ml of blood at intervals of one and a half hours before drug administration and: 0, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12 and 24 hours after administration is taken from volunteers. Determining the plasma concentration of ursodeoxycholic acid is done by liquid chromatography-mass spectrometry. The analysis of the results will be based on ANOVA and t-test statistical methods.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy volunteers between 18 and 50 years of age, non-smokers. Exclusion criteria: volunteers with blood pressure less than 90 over 60 mm Hg or higher than 140 over 90 mm Hg.

##### Intervention groups

The study includes two stages as intervention 1: including oral consumption of two 300 mg ursodeoxycholic acid capsules manufactured by Kimidaro Pharmaceutical Company in Iran and intervention 2: oral consumption of 2 300 mg ursodeoxycholic acid capsules

manufactured by Aurobindo Pharma LTD in India. This study will be repeated on fasting volunteers in a cross-sectional manner with an interval of four weeks.

##### Main outcome variables

Plasma concentration of the drug

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230222057495N5**

Registration date: **2023-06-05, 1402/03/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-06-05, 1402/03/15**

Update count: **0**

##### Registration date

2023-06-05, 1402/03/15

##### Registrant information

##### Name

Monireh Jalalipour

##### Name of organization / entity

Nikazma Pars Alborz company

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3731 8748

##### Email address

info@naplab.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-22, 1402/03/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Bioequivalence study of 300 mg ursodeoxycholic acid capsule of Kimidarou Pharmaceutical Company compared to 300 mg ursodeoxycholic acid of Aurobindo Pharma LTD, India on healthy volunteers

**Public title**

Bioequivalence study of 300 mg ursodeoxycholic acid capsules

**Purpose**

Other

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Healthy volunteers between the ages of 18 and 50 All candidates must be non-smokers Body mass index less than 30 kg per square meter

**Exclusion criteria:**

Blood pressure less than 90 over 60 mm Hg or more than 140 over 90 mm Hg Consumption of any drugs, alcohol or tobacco products within 2 weeks before receiving the drug

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

Bioequivalence

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **32**

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**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**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**

Research Institute of Pharmaceutical Sciences,  
Tehran University of Medical Sciences

**Street address**

Institute of Pharmaceutical Sciences, Faculty of  
Pharmacy, Tehran University of Medical Sciences,  
Porsina Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1417613151

**Approval date**

2023-05-17, 1402/02/27

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1402.028

**Health conditions studied**

1

**Description of health condition studied**

In the present study, no disease was investigated.

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Maximum plasma concentration of ursodeoxycholic acid

**Timepoint**

1,0.5 hours before and 0, 0.5, , 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8,  
10, 12 and 24 hours after drug administration

**Method of measurement**

Liquid chromatography-mass spectrometry

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group 1: includes the oral consumption of two 300 mg ursodeoxycholic acid capsules manufactured by Kimidarou Pharmaceutical Company of Iran on 24 healthy fasting volunteers. 5 ml of blood at intervals of one and a half hours before drug administration and: 0, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12 and 24 hours after administration. It is taken from volunteers. The cross-over study consists of two phases (oral consumption of two 300 mg ursodeoxycholic acid capsules per study and 2 times in total) with a four-week washout period (when the drug is completely removed from your blood).

Determining the plasma concentration of urosodeoxycholic acid is done by liquid chromatography-mass spectrometry. The analysis of the results will be based on ANOVA and t-test statistical methods.

**Category**

Other

**2****Description**

Intervention group 2: includes the oral consumption of two capsules of ursodeoxycholic acid 300 mg manufactured by Aurobindo Pharma LTD in India on 24 healthy fasting volunteers. 5 ml of blood at intervals of one and a half hours before drug administration and: 0, 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 12 and 24 hours after administration. It is taken from volunteers. The cross-over study consists of two phases (oral consumption of two 300 mg ursodeoxycholic acid capsules per study and 2 times in total) with a four-week washout period (when the drug is completely removed from your blood).

Determining the plasma concentration of urosodeoxycholic acid is done by liquid chromatography-mass spectrometry. The analysis of the results will be based on ANOVA and t-test statistical methods.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Nikazma Pars Alborz Laboratory

**Full name of responsible person**

Monireh Jalalipour

**Street address**

No. 419, Azadegan Square, Imam Khomeini Blvd.

**City**

Mahdasht Karaj

**Province**

Alborz

**Postal code**

3188913179

**Phone**

+98 26 3731 8748

**Email**

info@naplab.it

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Chemidarou Pharmaceutical Company

**Full name of responsible person**

Mojgan Aghajani

**Street address**

after Saipa repair shop, Kilometer 3, Tehran-Abali road, Sorkhe Hesar

**City**

Tehran

**Province**

Tehran

**Postal code**

1746773611

**Phone**

+98 21 7733 0291

**Fax**

+98 21 7733 6458

**Email**

office@chemidarou.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Chemidarou 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**

Nik Azma Pars Alborz laboratory

**Full name of responsible person**

Monireh Jalalipour

**Position**

Responsible Pharmacist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

No. 419, Imam Khomeini Boulevard, Azadegan Square

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

Nik Azma Pars Alborz laboratory

**Full name of responsible person**

Monireh Jalalipour

**Position**

Responsible Pharmacist

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Ph.D.

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**Email**

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Nik Azma Pars Alborz laboratory

**Full name of responsible person**

Monireh Jalalipour

**Position**

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**Latest degree**

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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**

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

**Data Dictionary**

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