Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 urosodeoxycholic 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 Kimidaro 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**

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
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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
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City
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Province
Alborz
Postal code
3188913179
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+98 26 3731 8748
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info@naplab.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
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