

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Bioequivalence Study of the Ursodeoxycholic acid 300-mg Capsule Produced by Ahran Tejarat Pharmaceutical Company compared to Ursoflor® by So Se PHARM.

Protocol summary

Study aim

Demonstration of bioequivalence of Ursodeoxycholic acid 300 mg Capsule of Ahran Tejarat Pharmaceutical Company with Ursoflor® Capsule manufactured by So Se PHARM company after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of Ursodeoxycholic acid 300-mg Capsule by Ahran Tejarat Co. with Ursoflor® (So Se PHARM Co.) in 24 healthy male volunteers in two groups under fasting condition.

Settings and conduct

Study place and the place for Blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive each of test or reference Ursodeoxycholic acid 300-mg Capsule in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 14 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 1 and 2 hours before dosing, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 48 and 72 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male subjects in the age range of 18-50 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: Subjects with BP $\leq$ 90/60 mm/Hg or BP $\geq$ 140/90 mm/Hg Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of TB, epilepsy, asthma, DM, psychosis or glaucoma and regular smoker.

Intervention groups

Intervention group 1: Ursodeoxycholic acid 300-mg Capsule by Ahran Tejarat Co. is the test product. Intervention group 2: Ursoflor® (So Se PHARM Co.) is the

reference product. In each period, 12 of 24 subjects will be given single dose of this product.

Main outcome variables

Peak Plasma Concentration (C_{max}); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N22**

Registration date: **2022-01-16, 1400/10/26**

Registration timing: **prospective**

Last update: **2022-01-16, 1400/10/26**

Update count: **0**

Registration date

2022-01-16, 1400/10/26

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-29, 1400/11/09

Expected recruitment end date

2022-04-29, 1401/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Bioequivalence Study of the Ursodeoxycholic acid 300-mg Capsule Produced by Ahran Tejarat Pharmaceutical Company compared to Ursoflor® by So Se PHARM.

Public title

Study of absorption and elimination rate of Ursodeoxycholic acid 300-mg Capsule in comparison with Ursodeoxycholic acid brand Capsule (Ursoflor®).

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The weight limit of each volunteer should be between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the consent form.

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Ursodeoxycholic acid or any ingredients. Subjects with BP $\leq$ 90/60 mm/Hg or BP $\geq$ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two weeks before dosing.

AgeFrom **18 years** old to **50 years** old**Gender**

Male

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 people 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 after entering the study, and 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 the 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**

Ethics committee of Tabriz University of Medical Science

Street address

Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-12-26, 1400/10/05

Ethics committee reference number

IR.TBZMED.REC.1400.997

Health conditions studied**1****Description of health condition studied**

Bioequivalence study

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Peak Plasma Concentration (Cmax)

Timepoint

At 1 and 2 hours before dosing, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 48 and 72 hours after dosing

Method of measurement

High-performance liquid chromatography—mass spectrometry (HPLC-MS)

Secondary outcomes**1****Description**

AUC (Area Under the Concentration-Time Curve)

Timepoint

At 1 and 2 hours before dosing, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 48 and 72 hours after dosing

Method of measurement

Using non-compartmental model of Win-Nonlin

Intervention groups

1

Description

Intervention group 1: In this group, volunteers are given a single oral dose of Ursodeoxycholic acid 300-mg Capsule produced by Ahran Tejarat Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, volunteers are given a single oral dose of Ursodeoxycholic acid 300-mg Capsule (Ursoflor), produced by So Se PHARM Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center

Full name of responsible person

Hamed Hamishehkar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahran Tejarat pharmaceutical Co

Full name of responsible person

Mostafa Etebari

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahran Tejarat 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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available