

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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<sub>max</sub>); 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)

##### Phone

+98 41 3336 2700

##### Email address

molavif@tbzmed.ac.ir

##### 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 ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two weeks before dosing.

**Age**

From **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

##### Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

##### City

Tabriz

##### Province

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##### Postal code

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##### Phone

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##### Email

hamishehkar.hamed@gmail.com

##### Web page address

<https://darc.tbzmed.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahran Tejarat pharmaceutical Co

##### Full name of responsible person

Mostafa Etebari

##### Street address

No. 27, Sharifi broders Ave, North gandi Ave,

##### City

Tehran

##### Province

Tehran

##### Postal code

123

##### Phone

+98 21 8865 0472

##### Fax

##### Email

Etebari@ahran.com

##### Web page address

##### 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

##### Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Jaber Emami

**Position**

Professor

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**Other areas of specialty/work**

Pharmaceutics

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Fatima Molavi

**Position**

Pharmacist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmaceutics

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Madani Hospital, Daneshgah Blvd, Tabriz, Iran

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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