

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Bioequivalence study of Ursodeoxycholic acid 300mg tablet manufactured by Ani Darman Co. compared with innovator product

#### Protocol summary

##### Study aim

Determination of bioequivalence in fasting state for 300 mg Ursodeoxy cholic acid tablet

##### Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy male volunteers will participate randomly in the study as two twelve-person study groups. Each volunteer will receive a single dose of drug in two periods. To randomly assign participants in two groups, the lottery method will be used.

##### Settings and conduct

After oral administration of one 300-mg tablet, 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. 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. This study will be conducted without blinding.

##### 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 product (Ursodeoxy cholic acid 300 mg tablet of Ani Darman) and Control group will receive a single dose of reference product (Ursodeoxy cholic acid 300 mg tablet of Sofar Co., Italy). Blood samples will be taken for 72 hours at the mentioned time points 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: **IRCT20210519051345N30**

Registration date: **2023-07-12, 1402/04/21**

Registration timing: **prospective**

Last update: **2023-07-12, 1402/04/21**

Update count: **0**

##### Registration date

2023-07-12, 1402/04/21

##### 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

2023-07-16, 1402/04/25

##### Expected recruitment end date

2024-03-19, 1402/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Bioequivalence study of Ursodeoxycholic acid 300mg tablet manufactured by Ani Darman Co. compared with innovator product

#### Public title

Investigating the in vivo bioequivalence of Ursodeoxycholic acid 300 mg tablet

#### 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, Tabriz University of Medical Sciences, Attar Neishabouri st., Golgasht st.

##### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

51664-14766

#### Approval date

2023-07-03, 1402/04/12

#### Ethics committee reference number

IR.TBZMED.REC.1402.276

## 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

At intervals between half and 72 hours after drug administration

#### Method of measurement

HPLC (High performance liquid chromatography)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: Intervention group will receive a single oral dose of test product (Ursodeoxy cholic acid 300 mg tablet manufactured by Ani DarmanCo.) 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 tablet manufactured by Sofar Co., Italy) 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, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.

**City**

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**Email**

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**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, Daneshgah st. Tabriz University of Medical Science

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**Phone**

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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**

Ani Darman 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, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.

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**Person responsible for scientific inquiries**

**Contact**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

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**Email**

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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**

Not applicable

**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