# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Jun 2026

## Bioequivalence Study of Ursodeoxycholic acid Tablets manufactured by Raihaneh and So-Se-Pharm Pharmaceutical companies

### Protocol summary

**Study aim**
To evaluate the pharmacokinetic parameters obtained after the single oral administration of the drug from either test or reference preparations

**Design**
This cross-over study will be done on 24 normal subjects. They were randomly allocated into two groups. After overnight fasting, they will receive one tablet from either Reihaneh or So-Se-Pharm pharmaceutical companies on two working days separated by a wash-out period of two weeks. They are not allowed to eat any consumption up to 3 hours at this time will receive a simple breakfast. Blood samples will be collected, at suitable intervals.

**Settings and conduct**
Kermanshah University of Medical Sciences, Medical Biology Research Center

**Participants/Inclusion and exclusion criteria**
Healthy volunteers

**Intervention groups**
Subjects receiving Rihaneh-manufactured drug Subjects receiving So Se Pharm-manufactured drug

**Main outcome variables**
Pharmacokinetic parameters include Elimination half-life, Area under the concentration-time curve up to sampling time, Area under the concentration-time curve up to infinity, Maximum concentration and Time to maximum concentration,

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20110523006565N2**
Registration date: **2022-02-05, 1400/11/16**
Registration timing: **prospective**

Last update: **2022-02-05, 1400/11/16**
Update count: **0**

**Registration date**
2022-02-05, 1400/11/16

**Registrant information**
**Name**
Gholam Reza Bahrami
**Name of organization / entity**
Kermanhsah University of Medical Science
**Country**
Iran (Islamic Republic of)
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+98 83 1428 1562
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-02-10, 1400/11/21

**Expected recruitment end date**
2022-02-24, 1400/12/05

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Bioequivalence Study of Ursodeoxycholic acid Tablets manufactured by Raihaneh and So-Se-Pharm Pharmaceutical companies

**Public title**
Bioequivalence Study of Ursodeoxycholic acid

**Purpose**
Other

**Inclusion/Exclusion criteria**
**Inclusion criteria:**

Written informed consent. Normal findings in the physical examination. Clinical laboratory values within 10% above or below the laboratory’s stated normal range To be a non-smoker

**Exclusion criteria:**

History of hypersensitivity to the study drug or related products Significant history or presence of gastrointestinal, liver or kidney disease, or any other condition known to interfere with the absorption, distribution, metabolism or excretion of common medications Any clinically significant illness during the 4 weeks prior to day 1 of this study Maintenance therapy with any drug, or history of drug dependence, alcohol abuse, or serious neurological or psychological disease Use of any systemic medication (including OTC preparations) within 14 days preceding day 1 of this study HIV and Hepatitis A, B and C positive subjects

**Age**

From **18 years** old to **45 years** old

**Gender**

Both

**Phase**

Bioequivalence

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

All the subjects will be received one tablet from either test or reference preparations on two working days separated by a wash-out period of two weeks.

**Placebo**

Not used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethical committe of Kermanshah University of Medical Sciences and Health Services

**Street address**

Beheshti blv, Kermanshah, Iran

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6714673159

**Approval date**

2021-10-11, 1400/07/19

**Ethics committee reference number**

50000522

## Health conditions studied

### 1

**Description of health condition studied**

Bioequivalence

**ICD-10 code**

**ICD-10 code description**

### 2

**Description of health condition studied**

Bioequivalence

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Plasma concentration

**Timepoint**

0 , 0.5, 1, 1.5 , 2, 2.5, 3, 3.5, 4, 5 , 6 , 8 , 10, 24 , 48 , 72

**Method of measurement**

Lc-mass mass

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Prescription of ursodesoxycholic acid ,300 mg Tablet manufactured by Reihaneh pharmaceutical company from Iran in the first week

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Medical Biology Research Center,

**Full name of responsible person**

Gholamreza Bahrami

**Street address**

Medical Biology Research Center, Kermanshah University of Medical Sciences, Kermanshah, Iran

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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Kermanshah University of Medical Sciences
**Full name of responsible person**
Dr. Reza Khodarahmi
**Street address**
Kermanshah University of Medical Sciences, Shahid Beheshti Bolv. Building No. 2
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Reihaneh 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**
Kermanshah University of Medical Sciences
**Full name of responsible person**
Gholamreza Bahrami
**Position**
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**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Not applicable
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable