Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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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gbahrami@kums.ac.ir

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
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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
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Gholamreza Bahrami
Position
Professor of Pharmacology
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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