

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Evaluation of bioequivalency of Ursodeoxycholic acid capsule of Ahran Tejarat Company compared to Ursoflor® on 24 volunteers.

Protocol summary

Study aim

Evaluation of biocompatibility of Ursodeoxycholic acid capsule of Ahran Tejarat Company compared to Ursoflor® on 24 volunteers.

Design

Evaluation of single dose of 300 mg Ursodiol capsule made by Ahran Tejarat company in comparison with 300 mg ® Ursoflor capsule of So.Se.PHARM company as a cross-reference product in 24 healthy fasting volunteers

Settings and conduct

1 -24 volunteers after their health is confirmed by the project doctor and signed the consent form is submitted to the project. 2 - In the fasting position Ursodiol capsule 300 mg (2) is prescribed with a glass of water (single Dose) 3 - At intervals of 0) before the administration of the drug), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 48, 72 hours after the administration of the drug, blood is taken from the volunteers. 4 - Each volunteer take 2 times the medication at least a week apart. 5 -Isolated plasmas transfer to the analysis laboratory to determine the amount of drug by HPLC method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 60 years, male, complete clinical health Exclusion criteria: Underlying diseases, hypertension, kidney, liver and gastrointestinal diseases, smoking and alcohol consumption, chronic drug use and temporary drug use less than 10 days after sampling

Intervention groups

Group No. 1 contain healthy volunteer that take the single dose 300 mg capsule Ursodeoxy cholic acid, Ahran Tejarat company as test. Group No. 2 contain healthy volunteer that take the single dose 300 mg capsule Ursoflor®, So.Se.PHARM company as reference.

Main outcome variables

Plasma drug concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120624010104N7**
Registration date: **2021-01-24, 1399/11/05**
Registration timing: **prospective**

Last update: **2021-01-24, 1399/11/05**

Update count: **0**

Registration date

2021-01-24, 1399/11/05

Registrant information

Name

Mehdi Ansari Dogaheh

Name of organization / entity

Faculty of Pharmacy, Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5001

Email address

mansari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of bioequivalency of Ursodeoxycholic acid

capsule of Ahran Tejarat Company compared to Ursoflor® on 24 volunteers.

Public title

Ursodeoxycholic acid in cholelithiasis

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Complete clinical health Age 18 to 60 years Male volunteers

Exclusion criteria:

Underlying diseases Hypertension Kidney Liver and gastrointestinal diseases Smoking and alcohol consumption Chronic drug use Temporary drug use less than 10 days after sampling

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **15**

Plasma drug concentration

Randomization (investigator's opinion)

N/A

Randomization description

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 Kerman University of Medical Sciences

Street address

Haft bagh alavi

City

Kerman

Province

Kerman

Postal code

123

Approval date

2021-01-03, 1399/10/14

Ethics committee reference number

IR.KMU.REC.1399.509

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination of drug concentration in plasma

Timepoint

Blood sampling during 0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 48, 72 hour after taking the drug

Method of measurement

UV-HPLC

Secondary outcomes

1

Description

Pharmacokinetic parameters

Timepoint

Immediately after the intervention

Method of measurement

Theoretically and using pharmacokinetic equations

Intervention groups

1

Description

Each volunteer take 2 times the medication at least a week apart. Intervention group: 1 -24 volunteers after their health is confirmed by the project doctor and signed the consent form is submitted to the project. 2 - In the fasting position 2 Ursodiol capsule 300 mg of Ahran Tejarat Company as a test product is prescribed with a glass of water (single Dose) 3 - At intervals of 0) before the administration of the drug), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 48, 72 hours after the administration of the drug, blood is taken from the volunteers. 4 -Isolated plasma transfer to the analysis laboratory to determine the amount of drug by HPLC method.

Category

Treatment - Drugs

2

Description

After at least a week apart: Intervention group: 1 -24 volunteers after their health is confirmed by the project

doctor and signed the consent form is submitted to the project. 2 - In the fasting position 2 Ursoflor® capsule 300 mg of company So.Se.PHARM as reference is prescribed with a glass of water (single Dose) 3 - At intervals of 0) before the administration of the drug), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 10, 24, 48, 72 hours after the administration of the drug, blood is taken from the volunteers. 4 -Isolated plasma transfer to the analysis laboratory to determine the amount of drug by HPLC method.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ansari

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2**Recruitment center****Name of recruitment center**

Sajjadih Charity Clinic

Full name of responsible person

Dr Samzadeh

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Joupar Blvd.

City

Kerman

Province

Kerman

Postal code

7619633353

Phone

+98 34 3321 0529

Email

mansari1345@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahran Tejarat Pharmaceutical Company

Full name of responsible person

Mostafa Etebari

Street address

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

City

Tehran

Province

Tehran

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Phone

+98 21 8865 0472

Email

Etebari@ahran.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Ahran Tejarat

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**

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ansari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mehdi Ansari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

No - There is not 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

No - There is not 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