Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Bioequivalence study of Ursodeoxycholic acid 300mg capsule manufactured by Mehr Darou Co. compared with innovator product

Protocol summary

Study aim
Determination of bioequivalence in fasting state for 300 mg Ursodeoxy cholic acid capsule

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 capsule, 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 capsule of MehDarou) and Control group will receive a single dose of reference product (Ursodeoxy cholic acid 300 mg capsule manufactured in Spain). 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: **IRCT20210519051345N47**
Registration date: **2024-01-27, 1402/11/07**
Registration timing: **prospective**

Last update: **2024-01-27, 1402/11/07**
Update count: **0**

Registration date
2024-01-27, 1402/11/07

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
2024-02-08, 1402/11/19

Expected recruitment end date
2024-11-09, 1403/08/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Bioequivalence study of Ursodeoxycholic acid 300mg capsule manufactured by Mehr Darou Co. compared with innovator product

Public title
Investigating the in vivo bioequivalence of Ursodeoxycholic acid 300 mg capsule
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 Committe, Tabriz University of Medical Sciences
Street address
Biomedical Research Committe, Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
51664-14766
Approval date
2024-01-14, 1402/10/24
Ethics committee reference number
IR.TBZMED.REC.1402.779

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 will receive a single oral dose of test product (Ursodeoxy cholic acid 300 mg capsule manufactured by Mehr DarouCo.) 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 capsule manufactured in Spain) 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

No.2 Central Building 3rd Floor, Daneshgah st. Tabriz University of Medical Science

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Phone

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Email

pzakeri@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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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

Mehr Darou 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

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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51664-14766

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

Position

Professor

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Ph.D.

Other areas of specialty/work
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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