

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Bioequivalence evaluation of Duloxetine Capsule 60 mg manufactured by Behin Tamin Rosamed company

Protocol summary

Study aim

Bioequivalence study of Duloxetine 60 mg Capsule manufactured by Behin Tamin Rosamed

Design

Clinical trials of single blind design of 24 volunteers with controlled group.

Settings and conduct

After selecting the volunteers, Duloxetine manufactured by Behin Tamin Rosamed company from Iran and Duloxetine manufactured by Eli Lilly company will be prescribed to them orally in two doses with an interval of 7 days. For example, if in the first period of the drug administration, the volunteer received the drug manufactured by Behin Tamin Rosamed company, in the next turn, the volunteer will receive drug manufactured by Eli Lilly company. Each time the amount of 6 cc of blood will be taken before drug administration and at times of 1, 2, 3, 4, 5/4, 5, 5/5, 6, 5/6, 7, 5/7, 8, 9, 10, 11, 12, 24, 36, 48, 72 hour after the medication is prescribed. The next sampling will 7 days later. In the second time, similar to the first time of drug administration, blood sampling will be done. Finally, the amount of drug in each sample is determined by Lc Mass Mass equipment.

Participants/Inclusion and exclusion criteria

Healthy volunteers, no history of diseases affecting the pharmacokinetic processes of the drug, no chronic or acute use of any drug at least 1 week before starting the study

Intervention groups

Volunteers will be divided into two groups: On the first week, group one will receive Duloxetine manufactured by Eli Lilly company and group number two will receive Duloxetine manufactured by Behin Tamin Rosamed company. On the second week, group number one will receive Duloxetine manufactured by Behin Tamin Rosamed company and group number two will receive Duloxetine manufactured by Eli Lilly company (cross over)

Main outcome variables

Maximum plasma concentration; area under the curve; the time taken to reach maximum plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200625047913N5**

Registration date: **2021-02-21, 1399/12/03**

Registration timing: **prospective**

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

Registration date

2021-02-21, 1399/12/03

Registrant information

Name

Tayebeh Ghari

Name of organization / entity

Hezareh Sevom Futuristic Pharmacist Company

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 2343

Email address

info@hezareh-co.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-02, 1399/12/12

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence evaluation of Duloxetine Capsule 60 mg manufactured by Behin Tamin Rosamed company

Public title

Bioequivalence evaluation of Duloxetine Capsule 60 mg manufactured by Behin Tamin Rosamed company

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18 to 45 years old Sex: Males and/or non-pregnant, non-lactating females Body mass index: 18.5 to 24.9 weight in kg/(height in meter) Able to communicate effectively with study personnel and willingness to follow the protocol requirements as evidenced by written informed consent A physical examination with no clinically significant finding and laboratory normal tests Do not take any chronic or acute medication for at least 1 week before the start of the study No history of diseases affecting the pharmacokinetic processes of the drug

Exclusion criteria:

History of allergic responses to Duloxetine or other related drugs, or any of its formulation ingredients Have significant diseases (which might compromise the haemopoietic, gastrointestinal, renal, hepatic, cardiovascular, respiratory, central nervous system, diabetes, psychosis or any other body system) or clinically significant abnormal findings during screening Smokers who smoke 10 or more cigarettes per day or 20 or more biddies per day or those who cannot refrain from smoking during the study period History or evidence of drug dependence or of alcoholism or of moderate alcohol use History of difficulty with donating blood or difficulty in accessibility of veins Volunteers who have received a known investigational drug within five elimination half life of the administered drug prior to the initial dose of study drug or who have participated in a clinical drug study or bioequivalence study within 90 days prior to the initial dose of study drug, whichever is greater found positive in urine test for drugs of abuse done before check-in of period History of difficulty in swallowing, or of any gastrointestinal disease which could affect drug absorption

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

A test and reference drug will be administrated to the volunteers in first week and one week after that. Volunteers do not know which medication they are taking each week.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of institute of pharmaceutical science of Tehran University of Medical Sciences

Street address

16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences, 2nd floor, Unit 1-219, Tehran- Iran.

City

تهران

Province

Tehran

Postal code

۱۴۱۷۶۱۴۴۱۱

Approval date

2021-01-26, 1399/11/07

Ethics committee reference number

IR.TUMS.TIPS.REC.1399.159

Health conditions studied**1****Description of health condition studied**

-

ICD-10 code

F33.0

ICD-10 code description

Major depressive disorder, recurrent, mild

Primary outcomes**1****Description**

Plasma concentration

Timepoint

1, 2, 3, 4, 5/4, 5, 5/5, 6, 5/6, 7, 5/7, 8, 9, 10, 11, 12, 24, 36, 48, 72 hour

Method of measurement

LC MS MS

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Prescription of Duloxetine 60 mg capsule manufactured by Behin Tamin Rosamed company from Iran in the first week

Category

Other

2**Description**

Control group: Prescription of Duloxetine 60 mg capsule manufactured by Eli Lilly company from America in the first week

Category

Other

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

Hezareh Sevom Futuristic Pharmacist Company

Full name of responsible person

Tayebeh Ghari

Street address

Unit 4, No. 81, Babak Bahrami st, After Zafar st, Tehran, Iran

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1968655815

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tayebehghari@gmail.com

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

Hezareh Sevom Futuristic Pharmacist

Full name of responsible person

Tayebeh Ghari

Street address

Unit 4, No 81, Babak Bahrami st, After Zafar st, Tehran, Iran.

City

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1968655815

Phone

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Email

info@hezareh-co.com

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

Yes

Title of funding source

Hezareh Sevom Futuristic Pharmacist

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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Alborze University of Medical Sciences, School of Pharmacy

Full name of responsible person

Faranak Salmannejad

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Alborze School of pharmacy, near Bahonar Hospital, Vali-e-asr st, Shora Blv, Karaj.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Alborze University of Medical Sciences, School of Pharmacy

Full name of responsible person

Faranak Salmannejad

Position

Assistant Professor

Latest degree

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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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

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To whom data/document is available

People working in industry and academia

Under which criteria data/document could be used

people working in industry and academia

From where data/document is obtainable

Sending email to info@hezareh-co.com - Sending fax to 00982188208678 - Calling to 00982188652343 -

Responsible person: Tayebeh Ghari

What processes are involved for a request to access data/document

Sending email to info@hezareh-co.com/ request evaluation/sending data

Comments