Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence study of dapoxetine 60 mg tablet of Sami Saz pharmaceutical company compared to dapoxetine 60 mg sample of Menarini company in England on healthy volunteers

Protocol summary

Study aim

Bioequivalence study of dapoxetine 60 mg tablet of Sami Saz pharmaceutical company compared to dapoxetine 60 mg sample of Menarini company in England on healthy volunteers

Design

he present clinical trial includes the study of the bioequivalence of Dapoxetine 60 mg tablets produced by Sami Saz Pharmaceutical Company compared to Dapoxetine 60 mg produced by Menarini Company in England, after administration to 24 healthy human volunteers, in two intervention groups, in a cross-over manner. , is not blinded and non-randomized.

Settings and conduct

The study is carried out at Nik Azma Pars Alborz Company, located in Mahdasht Karaj, Imam Khomeini Blvd., Azadegan Square, No. 419. The blinded cross-over study includes two stages (oral consumption of one 60 mg dapoxetine tablet per study and 2 times in total) with a one-week washout period on 24 fasting healthy volunteers. Blood samples are taken from the volunteers at certain intervals of drug consumption, and then the amount of dapoxetine in plasma is determined by liquid chromatography-mass spectrometry.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy volunteers between the ages of 18 and 55 should be non-smokers. Exclusion criteria: volunteers with blood pressure less than 90 over 60 mm Hg or higher than 140 over 90 mm Hg.

Intervention groups

The study includes two stages as intervention 1: including oral consumption of dapoxetine 60 mg tablets manufactured by Sami Saz Pharmaceutical Company in Iran and intervention 2: oral consumption of dapoxetine 60 mg tablets manufactured by Menarini Company in England. This study will be repeated on fasting volunteers in a cross-sectional manner with an interval of one week.

Main outcome variables

Maximum plasma concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057495N8**
Registration date: **2023-08-07, 1402/05/16**
Registration timing: **prospective**

Last update: **2023-08-07, 1402/05/16**
Update count: **0**

Registration date

2023-08-07, 1402/05/16

Registrant information

Name

Monireh Jalalipour

Name of organization / entity

Nikazma Pars Alborz company

Country

Iran (Islamic Republic of)

Phone

+98 26 3731 8748

Email address

info@naplab.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date

2024-08-10, 1403/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of dapoxetine 60 mg tablet of Sami Saz pharmaceutical company compared to dapoxetine 60 mg sample of Menarini company in England on healthy volunteers

Public title

Bioequivalence study of dapoxetine 60 mg tablet

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy volunteers aged between 18 and 55 years Body mass index less than 30 kg per square meter All candidates must be non-smokers

Exclusion criteria:

Blood pressure less than 90 over 60 mm Hg or more than 140 over 90 mm Hg Consumption of any drugs, alcohol or tobacco products within 2 weeks before receiving the drug

Age

From **18 years** old to **55 years** old

Gender

Both

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: **26**

Randomization (investigator's opinion)

Not randomized

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

Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences

Street address

Institute of Pharmaceutical Sciences, Faculty of Pharmacy, Tehran University of Medical Sciences, Porsina Street

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2023-07-31, 1402/05/09

Ethics committee reference number

IR.TUMS.TIPS.REC.1402.059

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The maximum plasma concentration of dapoxetine

Timepoint

before starting to take the drug and 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 24 and 48 hours after taking the drug

Method of measurement

Liquid chromatography-mass spectrometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: includes the oral intake of Dapoxetine 60 mg tablets of Sami Saz Pharmaceutical Company of Iran on 24 healthy fasting volunteers. 5 ml of blood will be taken from the volunteers at time intervals before the start of drug use and 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 24 and 48 hours after drug use. The cross-over study consists of two phases (oral administration of one 60 mg dapoxetine tablet per study for a total of 2 times) with a one-week washout period (when the drug is completely out of your blood). Dapoxetine plasma concentration is determined by liquid chromatography mass - spectrometry method. The analysis of the results will be based on ANOVA and t-test statistical methods.

Category

Other

2

Description
Intervention group 2: includes the oral consumption of 60 mg dapoxetine tablets from Menarini company of England, on 24 healthy fasting volunteers. 5 ml of blood is taken from the volunteers at time intervals before the start of drug administration and 0.5, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 24 and 48 hours after drug administration. The crossover study consists of two phases (prescribing one 60 mg dapoxetine tablet orally in each study for a total of 2 times) with a one-week washout period (when the drug is completely out of your blood). Dapoxetine plasma concentration is determined by liquid chromatography mass - spectrometry. The analysis of the results will be based on ANOVA and t-test statistical methods.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Nik Azma Pars Alborz Laboratory
Full name of responsible person
Monireh Jalalipour
Street address
No. 419, Azadegan Square, Imam Khomeini Boulevard
City
Mahdasht Karaj
Province
Alborz
Postal code
3188913179
Phone
+98 26 3731 8748
Email
info@naplab.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sami Saz Pharmaceutical Company
Full name of responsible person
Mohammad Ansari Mohseni
Street address
461, 9th St., Northern Effort Blvd, Toss Industrial Estate
City
Mashhad
Province
Razavi Khorasan
Postal code
9185113111
Phone
+98 51 3541 2969
Email
info@samisaz.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sami Saz 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
Nik Azma Pars Alborz laboratory
Full name of responsible person
Monireh Jalalipour
Position
Responsible Pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No. 419, Azadegan Square, Imam Khomeini Boulevard
City
Mahdasht Karaj
Province
Alborz
Postal code
3188913179
Phone
+98 26 3731 8748
Email
info@naplab.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Nik Azma Pars Alborz laboratory
Full name of responsible person
Monireh Jalalipour
Position
Responsible Pharmacist
Latest degree
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Other areas of specialty/work
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Province
Alborz
Postal code
3188913179
Phone
+98 26 3731 8748
Email
info@naplab.ir

Person responsible for updating data

Contact
Name of organization / entity
Nik Azma Pars Alborz laboratory
Full name of responsible person
Monireh Jalalipour
Position
Responsible Pharmacist
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No. 419, Azadegan Squar, Imam Khomeini Boulevard
City
Mahdasht Karaj
Province
Alborz
Postal code
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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
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available