

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

The 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. The study 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

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Province

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Person responsible for scientific inquiries

Contact

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Nik Azma Pars Alborz laboratory

Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity
Nik Azma Pars Alborz laboratory
Full name of responsible person
Monireh Jalalipour
Position
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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