Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Bioequivalence study of bisoprolol fumarate hydrochlorothiazide 10.25 mg tablets of Sami Saz pharmaceutical company compared to samples of bisoprolol fumarate 10 mg from Merck Germany and hydrochlorthiazide 25 mg from Juvise France on healthy volunteers

Protocol summary

Study aim

Bioequivalence study of bisoprolol fumarate hydrochlorothiazide 10/25 mg tablets of Sami Saz pharmaceutical company compared to samples of bisoprolol fumarate 10 mg from Merck Germany and hydrochlorthiazide 25 mg from Juvise France on healthy volunteers

Design

The current clinical trial includes the bioequivalence study of bisoprolol fumarate hydrochlorothiazide 10/25 mg tablets of Sami Saz Pharmaceutical Company compared to samples of bisoprolol fumarate 10 mg from Merck, Germany and hydrochlorthiazide 25 mg from Juvise, France, 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 tablet of bisoprolol fumarate hydrochlorothiazide 10/25 mg per study and a total of 2 times) with a one-week washout period on 24 fasting healthy volunteers. Then the obtained blood samples is analyzed.

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 intake of bisoprolol fumarate hydrochlorothiazide 10/25 mg tablets manufactured by Sami Saz Pharmaceutical Company of Iran and intervention 2: oral intake of bisoprolol fumarate tablets 10 mg manufactured by Merck Co., Germany and hydrochlorthiazide 25 mg manufactured by Iran Juvise is a French company. 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: **IRCT20230222057495N9**
Registration date: **2023-08-19, 1402/05/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-19, 1402/05/28**
Update count: **0**

Registration date

2023-08-19, 1402/05/28

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 bisoprolol fumarate hydrochlorothiazide 10.25 mg tablets of Sami Saz pharmaceutical company compared to samples of bisoprolol fumarate 10 mg from Merck Germany and hydrochlorthiazide 25 mg from Juvise France on healthy volunteers

Public title
Bioequivalence study of bisoprolol fumarate hydrochlorothiazide tablet 10/25 mg
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 on 60 mm Hg or more than 140 on 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: **30**

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.1402.060

Health conditions studied

1

Description of health condition studied

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maximum plasma concentrations of bisoprolol fumarate and hydrochlorothiazide
Timepoint
Before taking the medicine and: 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 7, 9, 10, 24, 34 and 48 hours after taking the medicine.
Method of measurement
Liquid chromatography-mass spectrometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: includes the oral intake of bisoprolol fumarate hydrochlorothiazide 10.25 mg tablets of Sami Saz Pharmaceutical Company of Iran on 24 fasting healthy volunteers. 5 ml of blood was taken from the volunteers at time intervals before starting to take the drug and 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 7, 9, 10, 24, 34 and 48 hours after taking the drug. can be The cross-

over study consists of two phases (oral administration of one tablet of bisoprolol fumarate hydrochlorothiazide 10.25 mg per study and a total of 2 times) with a one-week washout period (when the drug is completely removed from your blood). . Determination of plasma concentration of bisoprolol fumarate and hydrochlorothiazide is done 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 intake of bisoprolol fumarate 10 mg tablets from Merck, Germany and hydrochlorthiazide 25 mg from Juvise, France on 24 healthy fasting volunteers. 5 ml of blood was taken from the volunteers at time intervals before starting to take the drug and 0.5, 1, 1.5, 2, 2.5, 3, 4, 5, 7, 9, 10, 24, 34 and 48 hours after taking the drug. can be The cross-over study consists of two phases (oral administration of one tablet of bisoprolol fumarate hydrochlorothiazide 10.25 mg per study and a total of 2 times) with a one-week washout period (when the drug is completely removed from your blood). . Determination of plasma concentration of bisoprolol fumarate and hydrochlorothiazide is done by liquid chromatography mass-spectrometry method. 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

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Person responsible for scientific inquiries

Contact

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Nik Azma Pars Alborz laboratory

Full name of responsible person
Monireh Jalalipour

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Person responsible for updating data

Contact

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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