

# 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 hydrochlorothiazide 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 hydrochlorothiazide 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 hydrochlorothiazide 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 hydrochlorothiazide 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 hydrochlorothiazide 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**

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**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**

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**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

**Street address**

No. 419, Azadegan Square, Imam Khomeini Boulevard

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## 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**

Ph.D.

**Other areas of specialty/work**

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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**

Responsible Pharmacist

**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**

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