

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Bioequivalence evaluation of Metoprolol succinate Tablet 23.75 and 95 mg of Kushan Pharmed company

#### Protocol summary

##### Study aim

Bioequivalence study of Metoprolol succinate 23.75 and 95 Tablet 50 mg

##### Design

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

##### Settings and conduct

After selecting the volunteers, Metoprolol succinate drug manufactured by Kushan Pharmed Company from Iran and FDA approved Metoprolol succinate 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 Kushan Pharmed, in the next turn, the volunteer will receive FDA approved Metoprolol succinate. Each time the amount of 6 cc of blood before drug administration and at times of 0, 1, 2, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7, 7.5, 8, 9, 10, 11, 12, 14, 24, 36, 48 hour, It will be taken from the volunteers 24 and 48 hours 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 divided in two groups: On the first week, group one will receive metoprolol succinate manufactured by Kushan pharmed company and group number two will receive FDA approved metoprolol succinate. On the second week, group number one will receive FDA approved metoprolol succinate and group number two will receive metoprolol succinate manufactured by Kushan pharmed company (cross over)

##### Main outcome variables

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

#### General information

##### Reason for update

##### Acronym

BEMT (Bioequivalence evaluation metoprolol tablet)

##### IRCT registration information

IRCT registration number: **IRCT20200625047913N2**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **prospective**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

##### Registration date

2020-10-28, 1399/08/07

##### 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

2020-11-21, 1399/09/01

##### Expected recruitment end date

2020-12-05, 1399/09/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Bioequivalence evaluation of Metoprolol succinate Tablet 23.75 and 95 mg of Kushan Pharmed company

**Public title**

Bioequivalence evaluation of Metoprolol succinate Tablet 23.75 and 95 mg of Kushan Pharmed company

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

18 to 45 years old Sex: Males and/or non-pregnant, non-lactating females BMI: 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 Metoprolol succinate 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 History or presence of bronchial asthma 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**

کمیته اخلاق در پژوهش پژوهشکده علوم دارویی دانشگاه علوم پزشکی تهران

**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**

2020-10-05, 1399/07/14

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1399.085

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

-

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Plasma concentration

**Timepoint**

0, 1, 2, 3, 5/3, 4, 5/4, 5, 5/5, 6, 5/6, 7, 5/7, 8, 9, 10, 11, 12, 14, 24, 36, 48 hour

**Method of measurement**

## Secondary outcomes

1

### Description

-

### Timepoint

-

### Method of measurement

-

## Intervention groups

1

### Description

Intervention group: Prescription of Metoprolol succinate 23.75 and 95 mg tablets made by Kushan Pharmed company from Iran in the first week

### Category

Other

2

### Description

Control group: Prescription of Metoprolol succinate 23.75 and 95 mg FDA approved tablets made in the second 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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## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Hezareh Sevom Futuristic Pharmacist

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Tayebeh Ghari

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

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### 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

#### 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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salmannejad.f@gmail.com

## 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

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Ph.D.

**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Alborze University of Medical Sciences, School of Pharmacy

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**Position**  
Assistant professor

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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

from 2021

### To whom data/document is available

from 2021

### 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