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

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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 haemopoeitic, 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 asthmaSmokers 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.
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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

LC Mass/Mass

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
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Sponsors / Funding sources

1

Sponsor
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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
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Other areas of specialty/work
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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