

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Bioequivalence evaluation of Metoprolol succinate Tablet 47.5 mg of Raha Pharmaceutical company

Protocol summary

Study aim

Bioequivalence study of Metoprolol succinate manufactured by Raha pharmaceutical company

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 Raha pharmaceutical Company from Iran and FDA approved Metoprolol succinate will be prescribed to them orally in two doses with an interval of 7 days. Volunteers are blinded. For example, if in the first period of the drug administration, the volunteer received the drug manufactured by Raha pharmaceutical company, 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. Samples were collected in Anticoagulant tube collection tubes. The tubes were centrifuged and plasma samples were stored at -80 °C. 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 be divided in two groups: On the first week, group one will receive metoprolol succinate manufactured by Raha pharmaceutical 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 Raha pharmaceutical 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

IRCT registration information

IRCT registration number: **IRCT20200625047913N8**

Registration date: **2022-10-06, 1401/07/14**

Registration timing: **prospective**

Last update: **2022-10-06, 1401/07/14**

Update count: **0**

Registration date

2022-10-06, 1401/07/14

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

2022-10-19, 1401/07/27

Expected recruitment end date

2022-11-10, 1401/08/19

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bioequivalence evaluation of Metoprolol succinate Tablet 47.5 mg of Raha Pharmaceutical company

Public title
Bioequivalence evaluation of Metoprolol succinate Tablet 47.5 mg of Raha Pharmaceutical 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
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)

N/A

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

Ethics committee of institute of pharmaceutical science of Tehran University of Medical Sciences

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

Tehran

Province

Tehran

Postal code

۱۴۱۷۶۱۴۴۱۱

Approval date

2022-09-26, 1401/07/04

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.054

Health conditions studied

1

Description of health condition studied

-

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration

Timepoint

At the beginning of the study and 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 after the beginning of the study

Method of measurement

LC Mass/Mass

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Metoprolol succinate 47.5 mg tablets made by Raha pharmaceutical company from Iran will prescribe in the first week at fast condition and blood samples will draw in determined intervals.

Category

N/A

2

Description

Control group: Metoprolol succinate 47.5 mg tablets made by Astrazerneca pharmaceutical company from America will prescribe in the second week at fast condition and blood samples will draw in determined intervals.

Category

N/A

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.

City

Tehran

Province

Tehran

Postal code

1968655815

Phone

+98 21 8865 2343

Fax

+98 21 8820 8678

Email

info@hezareh-co.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hezareh Sevom Futuristic Pharmacist

Full name of responsible person

Tayebeh Ghari

Street address

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

City

Tehran

Province

Tehran

Postal code

1968655815

Phone

+98 21 8865 2343

Email

info@hezareh-co.com

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, School of Pharmacy

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 Bamonar Hospital, Vali-e-asr st, Shora Blv, Karaj.

City

Karaj

Province

Alborz

Postal code

3154686689

Phone

+98 26 3256 7175

Email

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

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Alborze School of pharmacy, near Bamonar Hospital, Vali-e-asr st, Shora Blv, Karaj.

City

Karaj

Province

Alborz

Postal code

3154686689

Phone

+98 26 3256 7175

Email

salmannejad.f@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Alborze University of Medical Sciences, School of Pharmacy

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 Bamonar Hospital, Vali-e-asr st, Shora Blv, Karaj.

City

Karaj

Province

Alborz

Postal code

3154686689

Phone

+98 26 3256 7175

Email

salmannejad.f@gmail.com

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 2023

To whom data/document is available

People working in industry and academia

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: Tayebah Ghari

What processes are involved for a request to access data/document

Sending email to info@hezareh-co.com/ request evaluation/sending data

Comments