Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Randomized, single-dose, crossover comparative bioequivalence study of Metoprolol succinate 95 mg ER tablets of Actoverco and Recordati Pharma GmbH in 24 healthy male under fasting conditions

Protocol summary

Study aim

This study was performed to compare the pharmacokinetics and invivo parameters of Metoprolol Succinate 95 mg ER formulation as a test product with Beloc-Zok® 95 mg tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Metoprolol succinate 95 mg. tablets of Actoverco and Recordati Pharma GmbH Limited Co. in 24 healthy male under fasting

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods were separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 18 – 40 years of age and Body Mass Index (BMI) between 18.5-30 (inclusive), calculated as kg/m2 Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Known hypersensitivity or idiosyncratic reaction to Metoprolol succinate or inactive ingredients. History or current bronchial asthma.

Intervention groups

Intervention group: Intervention group (test): Metoprolol Succinate 95 mg tablet, produced by Actoverco. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. Intervention group (Reference): Metoprolol Succinate 95 mg tablet, produced by Lundbeck Limited is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N11**
Registration date: **2021-10-20, 1400/07/28**
Registration timing: **retrospective**

Last update: **2021-10-20, 1400/07/28**
Update count: **0**

Registration date

2021-10-20, 1400/07/28

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 7026

Email address

info@tavaninstitute.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-04, 1399/09/14

Expected recruitment end date

2020-12-18, 1399/09/28

Actual recruitment start date

2020-12-04, 1399/09/14

Actual recruitment end date

2020-12-18, 1399/09/28

Trial completion date

2021-06-21, 1400/03/31

Scientific title
Randomized, single-dose, crossover comparative bioequivalence study of Metoprolol succinate 95 mg ER tablets of Actoverco and Recordati Pharma GmbH in 24 healthy male under fasting conditions

Public title
Bioequivalence study of Metoprolol succinate 95 mg ER tablets in 24 healthy male under fasting conditions

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy subjects (male) between 18 – 40 years of age and Body Mass Index (BMI) between 18.5-30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Metoprolol succinate or inactive ingredients. History or current bronchial asthma. Subjects who has used any drug including prescription drugs (within 14 days) or Over-The-Counter (OTC) drugs within 7 days prior to the start of the study and might need drug intake during study period; History of alcohol or drug abuse A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study

Age
From **18 years** old to **40 years** old

Gender
Male

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: **36**
In each period, 18 blood samples are collected from each subject and this study includes 2 periods.
Actual sample size reached: **24**
More than 1 sample in each individual
Actual sample size in each individual: **36**
In each period, 18 blood samples are collected from each subject and this study includes 2 periods

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization schedule is generated with the BEAR statistical software (Release V2.7.7). Each volunteer is randomly assigned to one of the 2 different sequence of treatments according to their entrance number to study which is allocated after screening.

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 Shahid Beheshti University of Medical Sciences

Street address
Sharif innovation station, North Habibollah, Hosseini Squ., Teymoury St., Tarasht

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2020-02-03, 1398/11/14

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1398.267

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic (Actoverco.) Metoprolol Succinate 95 mg tablet with brand Beloc-Zok® Recordati Pharma GmbH ER 95 mg tablet.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
During 2 months after intervention

Method of measurement
Using non-compartmental model of Win-Nonlin professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

During 2 months after intervention

Method of measurement

using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description

Intervention group: Intervention group: (test): Metoprolol Succinate 95 mg tablet, produced by Actoverco. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.

Category

Treatment - Drugs

2

Description

Intervention group: (reference): Beloc-Zok 95 mg tablet, produced by Recordati Pharma GmbH. is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Farabi Clinic

Full name of responsible person

ابراهیم سیاه پوش

Street address

No. 57, Shemshad alley, Sallor city

City

Eslamshahr

Province

Tehran

Postal code

4635314588

Phone

+98 21 9253 5647

Email

mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Actover pharmaceutical co.

Full name of responsible person

Nahaleh Naraghi

Street address

58 plaque, 8th St., Gisha

City

Tehran

Province

Tehran

Postal code

1446863914

Phone

+98 21 4162 7000

Email

info@actoverco.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Actover pharmaceutical co.

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

Noor Research & Development Institute

Full name of responsible person

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

pharmacy

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tavan Institute

Full name of responsible person
Seyed Mohsen Foroutan

Position
Principal investigator

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
Tavan Institute

Full name of responsible person
علی آقایی

Position
Master

Latest degree
Master

Other areas of specialty/work
pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It's not specified yet

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available