Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative bioequivalence study of Esomeprazole 40 mg E.C Capsule of ActoverCo. and ®ESOMEP of HEXAL in 24 healthy subjects under fasting condition

Protocol summary

Study aim
This study will be performed to compare the pharmacokinetics and invivo parameters of Esomeprazole 40 mg E.C. Capsule formulation as a test product with ®ESOMEP 40 mg E.C Capsule formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design
Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

Settings and conduct
In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). Two dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Healthy subjects (male) between 18–55 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 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. Exclusion Criteria: Subjects with known allergy to the products tested; Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period.

Intervention groups
Intervention group 1: Esomeprazole 40 mg E.C. Capsule, produced by Actover Co. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: ®ESOMEP 40 mg E.C Capsule, produced by HEXAL is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables
Peak Plasma Concentration

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180620040164N92**
Registration date: **2025-05-21, 1404/02/31**
Registration timing: **prospective**

Last update: **2025-05-21, 1404/02/31**
Update count: **0**

Registration date
2025-05-21, 1404/02/31

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
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-05-30, 1404/03/09
Expected recruitment end date
2025-06-06, 1404/03/16
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of Esomeprazole 40 mg E.C Capsule of ActoverCo. and ®ESOMEP of HEXAL in 24 healthy subjects under fasting condition

Public title
Comparative in vivo evaluation of 2 formulations of Esomeprazole 40 mg E.C Capsule
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subjects (male) between 18– 55 years of age. Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 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:
Subjects with known allergy to the products tested. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who has used any prescription or OTC drugs 14 days prior to the initiation of study and unable to refrain from the concomitant medications. History of alcohol or drug abuse. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. 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 **55 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.
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
Niayesh complex, No 2660, Valiasr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2025-04-28, 1404/02/08
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1404.009

Health conditions studied

1

Description of health condition studied
Gastro-esophageal reflux disease without esophagitis
ICD-10 code
K21.9
ICD-10 code description
Gastro-esophageal reflux disease without esophagitis

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
14 blood samples will be withdrawn pre-dose, 0.25, 0.5, 0.75, 1, 1.25, 1.5, 1.75, 2, 3, 4, 6, 8, 12
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

14 blood samples will be withdrawn pre-dose, 0.25, 0.5, 0.75, 1, 1.25, 1.5, 1.75, 2, 3, 4, 6, 8, 12

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: Esomeprazole 40 mg E.C. Capsule, produced by ActoverCo. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Category

Treatment - Drugs

2

Description

Intervention group: Esomep 40 mg E.C. Capsule, produced by HEXAL is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor Research & Development Institute (Tavan)

Full name of responsible person

Behzad Montaha Sangari

Street address

Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

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1459926609

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Actoverco.

Full name of responsible person

Reza Karimi Mostofi

Street address

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Postal code

3197996184

Phone

+98 21 4163 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

Actoverco.

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 and educational institute (Tavan)

Full name of responsible person

Behzad Montaha Sangari

Position

CEO

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mohsen Foroutan

Position
CEO

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
Noor research and educational institute (Tavan)

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Behzad Montaha Sangari

Position
CEO

Latest degree
Medical doctor

Other areas of specialty/work
Medical 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 undetermind yet.

Study Protocol
No - There is not 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