Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jul 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Esomeprazole 10mg sachet produced by Razan Pharmed Iranian pharmaceutical Co versus Nexium® (AstraZeneca company) in 24 healthy males under fasting conditions

Protocol summary

Study aim
To demonstrate bioequivalence of single dose test formulation of Razan Pharmed Iranian Esomeprazole 10 mg sachet versus Nexium®(AstraZeneca Co.)

Design
Single dose, randomized and crossover bioequivalence study of Esomeprazole 10 mg sachet by Razan Pharmed Iranian Co. with Nexium® (AstraZeneca Co.) in 24 healthy male in two groups under fasting condition.

Settings and conduct
Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. Place for Blood and plasma sample analysis: Imam Reza Medical Research and Trainning Hospital. 24 healthy male volunteers received each of two test or reference Esomeprazole 10 mg sachet in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before receiving the drug and 48 hours after that at determined time points: 0.5، 1، 1.5، 2، 2.5، 3، 3.5، 4، 5، 6، 7، 8، 10، 12 and 24 hours.

Participants/Inclusion and exclusion criteria
Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18.5-30. Exclusion criteria: Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of TB, epilepsy, asthma, DM, psychosis or glaucoma and regular smoker.

Intervention groups
Intervention group (Test): Esomeprazole 10 mg sachet by Razan Pharmed Iranian Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. Control group (Reference): Nexium® (AstraZeneca Co.) is the reference product. In each period, 12 of 24 subjects will be given single dose of this product.

Main outcome variables
Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update
Editing information

Acronym

IRCT registration information
IRCT registration number: **IRCT20200407046981N12**
Registration date: **2021-08-23, 1400/06/01**
Registration timing: **prospective**

Last update: **2021-08-25, 1400/06/03**
Update count: **1**

Registration date
2021-08-23, 1400/06/01

Registrant information

Name
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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-21, 1400/06/30
Expected recruitment end date
2021-12-21, 1400/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Randomized, single-dose, crossover comparative bioequivalence study of the Esomeprazole 10mg sachet produced by Razan Pharmed Iranian pharmaceutical Co versus Nexium® (AstraZeneca company) in 24 healthy males under fasting conditions

Public title
Study of absorption and elimination rate of Esomeprazole 10 mg sachet in comparison with standard sachet of Esomeprazole (Nexium®).
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
The weight limit for each volunteer is between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed.
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Esomeprazole or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two week before dosing.
Age
From **18 years** old to **60 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: **2**
Candidates of the sequences must take one of the Iranian or brand drugs, if the first sequence of the volunteers received the domestic drug after the washout period, they must receive the brand drug. In fact,every single volunteers is used as control for himself.
Randomization (investigator's opinion)
Randomized
Randomization description
First, a table of random numbers from 1 to 24 is created. The table numbers are assigned to individuals in the order in which the candidates enter the list on the day of the experiment, and the candidates in two groups with numbers 1-12 and numbers 13-24 will receive reference and test medicine, respectively.
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 Tabriz University of Medical Science
Street address
Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-08-02, 1400/05/11
Ethics committee reference number
IR.TBZMED.REC.1400.471

Health conditions studied

1

Description of health condition studied
In this study, the disease is not examined. The subject of the study is the bioequivalence study of the Esomeprazole 10 mg of test and reference in healthy volunteers.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
At 0 (before dosing), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 7, 8, 10, 12 and 24 hour after dosing
Method of measurement
High-performance liquid chromatography—mass spectrometry (HPLC-MS)

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) or SPSS

Intervention groups

1

Description
Intervention group (Test): Esomeprazole 10 mg sachet, produced by Razan Pharmed Iranian Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. In the second period, after washout, this group (test) will be in the reference group and will use brand drug (Nexium10mg).
Category
Treatment - Drugs

2

Description
Intervention group (Reference): Esomeprazole 10mg sachet (Nexium), produced by AstraZeneca Company is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. In the second period, after washout, this group (Reference) will be in the test group and will use domestic Esomeprazole 10mg sachet.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
شرکت داروسازی رازان فارمد ایرانیان
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
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Position
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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
There is no further information

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