Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparative bioequivalence study of the Omeprazole 10-mg Sachet manufactured by Kimia Kala Razi Pharmaceutical Company versus Nexium® (AstraZeneca Company)

Protocol summary

Study aim

Demonstration of bioequivalence of omeprazole 10 mg sachet of Kimia Kala Razi Pharmaceutical Company with Nexium® sachet manufactured by AstraZeneca company after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of omeprazole 10-mg sachet by Kimia Kala Razi Co. with Nexium® (AstraZeneca Co.) in 24 healthy male volunteers in two groups under fasting condition.

Settings and conduct

Study place and the place for Blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive each of two test or reference omeprazole 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 and after receiving the drug at predetermined time points: 0, 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

Inclusion 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 1: Omeprazole 10-mg sachet by Kimia Kala Razi Co. is the test product. Intervention group 2: 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

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N20**
Registration date: **2021-10-22, 1400/07/30**
Registration timing: **prospective**

Last update: **2021-10-22, 1400/07/30**
Update count: **0**

Registration date

2021-10-22, 1400/07/30

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of the Omeprazole 10-mg Sachet manufactured by Kimia Kala Razi Pharmaceutical Company versus Nexium® (AstraZeneca Company)

Public title
Study of absorption and elimination rate of omeprazole 10-mg Sachet in comparison with omeprazole brand Sachet (Nexium®).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The weight limit of each volunteer should be 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. Candidates who have consented to the consent form.
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to omeprazole 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 weeks 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**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of the both groups will change for the second period.
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
2021-10-04, 1400/07/12
Ethics committee reference number
IR.TBZMED.REC.1400.618

Health conditions studied

1

Description of health condition studied
Bioequivalence study
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
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
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Omeprazole 10-mg sachet produced by Kimia Kala Razi Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Omeprazole 10-mg sachet (Nexium), produced by AstraZeneca Company (Brand). 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
Drug Applied Research Center
Full name of responsible person
Dr Hamed Hamishehkar
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Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kimia Kala Razi Pharmaceutical Company
Full name of responsible person
Dr Arsalan Pashapour
Street address
First floor, No. 412, Corner of 54th Street, Seyed Jamaluddin Asadabadi, Tehran, Iran
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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
Kimia Kala Razi Pharmaceutical Company
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
Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
Position
Professor
Latest degree
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Other areas of specialty/work
Pharmaceutics
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PhD student of Pharmaceutics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

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

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

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