

# 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  $\leq$  90/60 mm/Hg or BP  $\geq$  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)

##### Phone

+98 41 3336 2700

##### Email address

molavif@tbzmed.ac.ir

##### 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  $\leq$  90/60 mm/Hg or BP  $\geq$  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

##### Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665811

##### Phone

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##### Email

hamishehkar.hamed@gmail.com

##### Web page address

<https://darc.tbzmed.ac.ir/>

## 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1111111111

#### Phone

+98 21 8803 9651

#### Fax

#### Email

Info@Kimiakalarazi.com

#### 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

Ph.D.

##### Other areas of specialty/work

Pharmaceutics

##### Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

**Full name of responsible person**

Jaber Emami

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Pharmaceutics

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fatima Molavi

**Position**

PhD student of Pharmaceutics

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pharmaceutics

**Street address**

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Madani Hospital, Daneshgah Blvd, Tabriz, Iran

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**Email**

Molavif@tbzmed.ac.ir

**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