Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A study to compare the relative bioavailability of Temad and Pfizer formulations of esomeprazole magnesium 40 mg capsules in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim

The study aims to evaluate the bioequivalence of esomeprazole magnesium 40 mg capsules produced by two different pharmaceutical companies under fasting condition.

Design

This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacokinetic of esomeprazole magnesium and Nexium® capsules in 24 healthy adults volunteers. Volunteers will be sorted and receive a number from 1 to 24. In the first phase of the study, 12 volunteers will receive esomeprazole magnesium manufactured by Temad and the remaining 12 volunteers will receive Nexium® produced by Pfizer company. The administered drugs will be replaced by each other in the second phase of the study.

Settings and conduct

The dose administration in fasting condition and sample collection in different time points in S. Motahhari hospital (Gonbade Kavous, Iran) and plasma drug analysis by high-performance liquid chromatography technique will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria:18-55 years of age. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. Good health at screening. Exclusion criteria: History of any drug hypersensitivity or intolerance. Significant history or current evidence of chronic disease. Receipt of any drug as part of a research study within 30 days prior to the present study.

Intervention groups

First intervention group: A single 40 mg oral dose of esomeprazole magnesium (1 capsule) manufactured by Temad company to 12 subjects. Second intervention group: A single 40 mg oral dose of Nexium (1 capsule) manufactured by Pfizer company to 12 subjects. Since in this study, the volunteers will receive both Test and Reference drugs, each volunteer will act as his own control.

Main outcome variables

Drug plasma concentration; Area under the plasma concentration-time curve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130626013776N34**
Registration date: **2020-12-19, 1399/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-19, 1399/09/29**
Update count: **0**

Registration date

2020-12-19, 1399/09/29

Registrant information

Name
Hossein Amini
Name of organization / entity
Golestan University of Medical Sciences
Country
Iran (Islamic Republic of)
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hamini@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date
2021-12-19, 1400/09/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A study to compare the relative bioavailability of Temad and Pfizer formulations of esomeprazole magnesium 40 mg capsules in 24 healthy adult volunteers under fasting conditions

Public title
Bioequivalence study of esomeprazole magnesium 40 mg capsules
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
18-55 years of age. The subject is able and willing to provide signed informed consent. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. The subject has stable residence and telephone. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening.
Exclusion criteria:
History of allergy or sensitivity to esomeprazole magnesium. History of any drug hypersensitivity or intolerance which, in the opinion of the investigator,would compromise the safety of the subject of the study. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. Presence of gastrointestinal disease or history of malabsorption within the last year. History of a medical disorders occurring within the last year that required hospitalization or medication. Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. Receipt of any drug as part of a research study within 30 days prior to the present study. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.
Age
From **18 years** old to **55 years** old
Gender
Both

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: **13**
A volume of 2 ml of blood is obtained in each sampling time through a venous cannula
Randomization (investigator's opinion)
Randomized
Randomization description
Each subject is identified by a number from 1 to 24. This number is allocated according to their entrance to volunteers' list in the screening day. According to the crossover design of the study, the twenty four participants randomized into two sequences of Test/Reference and Reference/Test products using command of rand in the Excel program.
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 Golestan University of Medical Sciences
Street address
Falsafi Building, Sari Road Km 5
City
Gorgan
Province
Golestan
Postal code
4934174515
Approval date
2020-11-15, 1399/08/25
Ethics committee reference number
IR.GOUMS.REC.1399.277

Health conditions studied

1

Description of health condition studied
.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Drug plasma concentration
Timepoint
At time zero and 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 and 12 h after drug administration
Method of measurement

Blood sampling and measurement of drug concentrations by HPLC

Secondary outcomes

1

Description
Plasma half-life
Timepoint
From the terminal 6 hours of plasma concentration-time profile
Method of measurement
Blood sampling and drug analysis by HPLC

Intervention groups

1

Description
Intervention group: Oral administration of a single 40 mg dose of Esmoprazole (1 capsule) manufactured by Temad to healthy volunteers under fasting condition in the morning of the experiment day
Category
Treatment - Drugs

2

Description
Intervention group: Oral administration of a single 40 mg dose of Nexium (1 capsule) manufactured by Pfizer to healthy volunteers under fasting condition in the morning of the experiment day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center, S. Motahhari Hospital
Full name of responsible person
Yahya Naserifard
Street address
Taleghani Street
City
Gonbade Kavous
Province
Golestan
Postal code
4916817693
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+98 17 3252 5972
Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Temad Company
Full name of responsible person
Dr. Moradi
Street address
Tehran, Makhsoos Road, km 28
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Province
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Postal code
3164816478
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Email
info@temad.com
Web page address
Grant name
Bioequivalence Study of Esomeprazole
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Temad 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
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
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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
Data are confidential and need permission from the company.
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