Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A study to compare the relative bioavailability of EadehDaruTeb and AstraZeneca formulations of esomeprazole magnesium 10 mg sachet in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim

The study aims to evaluate the bioequivalence of esomeprazole 10 mg sachets produced by two different pharmaceutical companies under fasting conditions

Design

This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacokinetics of esomeprazole and Nexium® sachets in 24 healthy adult 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 manufactured by EadehDaruTeb and the remaining 12 volunteers will receive Nexium® produced by AstraZeneca company. The administered drugs will be replaced to another group in the second phase of the study.

Settings and conduct

The dose administration and subsequent sample collection will be performed in Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 18-55 years; subject available for the entire study period; willingness to adhere to protocol requirements as evidenced by written informed consent; good health at screening. Exclusion criteria: History of use 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 20 mg oral dose of esomeprazole sachet manufactured by EadehDaruTeb company to 12 subjects. Second intervention group: A single 20 mg oral dose of Nexium sachet manufactured by AstraZeneca company to 12 subjects. Since the volunteers will receive both test and reference drugs in this study, 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: **IRCT20130626013776N74**
Registration date: **2022-07-23, 1401/05/01**
Registration timing: **prospective**

Last update: **2022-07-23, 1401/05/01**
Update count: **0**

Registration date

2022-07-23, 1401/05/01

Registrant information

Name

Hossein Amini

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1442 1651

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A study to compare the relative bioavailability of EadehDaruTeb and AstraZeneca formulations of esomeprazole magnesium 10 mg sachet in 24 healthy adult volunteers under fasting conditions

Public title
Bioequivalence study of esomeprazole magnesium 10 mg sachet
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. Willing to adhere to protocol requirements as evidenced by written informed consent. The subject has a 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. 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: **2**
In a crossover design, each person is its own control and receives two different interventions
Randomization (investigator's opinion)
Randomized
Randomization description
A pot sampling method will be used in this study. 12 papers are labeled "Reference Product" and 12 papers are written as "Test Product". The papers are then placed in sealed envelopes, and participants randomly select a paper and will be placed in the Reference or Test groups.
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 2
City
Gorgan
Province
Golestan
Postal code
4934174515
Approval date
2022-06-12, 1401/03/22
Ethics committee reference number
IR.GOUMS.REC.1401.107

Health conditions studied

1

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

Primary outcomes

1

Description
Maxium plasma drug 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 high-performance liquid chromatography

2

Description
Area under plasma drug concentration-time curve

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 high-performance liquid chromatography

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 high-performance liquid chromatography method

Intervention groups

1

Description
Intervention group 1: Oral administration of a single 20 mg dose of esomeprazole sachet manufactured by EadehDaruTeb to healthy volunteers under fasting conditions in the morning of the experiment day
Category
Treatment - Drugs

2

Description
Intervention group 2: Oral administration of a single 20 mg dose of Nexium sachet manufactured by AstraZeneca to healthy volunteers under fasting conditions 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

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
EadehDaruTeb Pharmaceuticals
Full name of responsible person
Dr. Ali Mohammadi Silabi
Street address
Unit 3, No.9, Dr. Gharib Street
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Province
Tehran
Postal code
1419831985
Phone
+98 21 6692 5241
Fax
+98 21 6692 5789
Email
info@edtpharma.com
Web page address
http://edtpharma.com
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
EadehDaruTeb Pharmaceuticals
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
Latest degree
Ph.D.
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
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