

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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

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

#### 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

#### 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

##### Email address

hamini@sbmu.ac.ir

##### 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 science

**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

**Phone**

+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

**City**

Tehran

**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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**City**

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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