

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

A study to compare the relative bioavailability of Dorsa Darou 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 conditions

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 Dorsa Darou 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 and subsequent sample collection will be performed in S. Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-50 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 Dorsa Darou 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: **IRCT20130626013776N23**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **prospective**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

Registration date

2020-07-04, 1399/04/14

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

2020-07-22, 1399/05/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of Dorsa Darou 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 science

Inclusion/Exclusion criteria**Inclusion criteria:**

18-50 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 **50 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 2

City

Goragn

Province

Golestan

Postal code

4934174515

Approval date

2020-05-31, 1399/03/11

Ethics committee reference number

IR.GOUMS.REC.1399.050

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

2

Description

Area under plasma 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 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 Dorsa 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

Phone

+98 17 3252 5972

Fax

+98 17 3252 5972

Email

haminhplc@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dorsa Darou Company

Full name of responsible person

Dr. Majid Jamshidi

Street address

Dorsa Bldg., No. 1, Khajoo St., Salehi Blvd., Jenah Expy., Azadi Sq.,

City

Tehran

Province

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Postal code

1459666876

Phone

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Fax

+98 26 3777 5148

Email

jamshidi888@gmail.com

Web page address

<http://dorsapharma.com/>

Grant name

Bioequivalence Study of Esmoprazole

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dorsa Darou 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

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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