# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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

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**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 scienece
**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
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**Province**
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4916817693
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**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**
Tehran
**Postal code**
1459666876
**Phone**
+98 26 3777 5149
**Fax**
+98 26 3777 5148
**Email**
jamshidi888@gmail.com
**Web page address**
http://dorsapharma.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**
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