Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

A study to compare the relative bioavailability of Temad and Takeda formulations of pantoprazole 40 mg Capsules in 24 healthy adult volunteers under fasting conditions

Protocol summary

Study aim
The study aims to evaluate the bioequivalence of pantoprazole 40 mg capsule 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 pantoprazole and Pantozol® 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 pantoprazole manufactured by Temad and the remaining 12 volunteers will receive Pantozol® produced by Takeda 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:18-55 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 pantoprazole (1 capsule) manufactured by Temad company to 12 subjects. Second intervention group: A single 40 mg oral dose of Pantozol (1 capsule) manufactured by Takeda 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: **IRCT20130626013776N31**
Registration date: **2020-11-30, 1399/09/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-30, 1399/09/10**
Update count: **0**

Registration date
2020-11-30, 1399/09/10

Registrant information

Name
Hossein Amini

Name of organization / entity
Golestan University of Medical Sciences

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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
2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of Temad and Takeda formulations of pantoprazole 40 mg Capsules in 24 healthy adult volunteers under fasting conditions

Public title

Bioequivalence study of pantoprazole 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 pantoprazole. 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. 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 2

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-11-15, 1399/08/25

Ethics committee reference number

IR.GOUMS.REC.1399.279

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 high-performance liquid chromatography

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 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

Intervention groups

1

Description

Intervention group: Oral administration of a single 40 mg dose of pantoprazole (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 Pantozol (1 capsule) manufactured by Takeda 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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Gonbade Kavous

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Golestan

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4916817693

Phone

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haminhplc@yahoo.com

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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Tehran

Province

Tehran

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3164816478

Phone

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Fax

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info@temad.com

Grant name

Bioequivalence Study of pantoprazole

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

Latest degree

Ph.D.

Other areas of specialty/work

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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