

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparative bioequivalence study of two different Pantoprazole 40mg formulations (Exir Pharmaceutical Company & reference) in 24 Iranian volunteers

Protocol summary

Study aim

This study, as part of the curriculum of bioequivalence tests of domestic production, evaluates the bioequivalence of 40 mg Pantoprazole enteric coated tablet manufactured by Exir Pharmaceutical Company with its reference sample

Design

Bioequivalency study of Pantoprazole 40 mg tablet (Exir Pharmaceutical Company) and reference product of Pantozol (Takeda Company) are evaluated in 24 healthy volunteers. This study was cross-over, random, and double-blind.

Settings and conduct

This study is carried out in the central laboratory of the Hamadan School of Pharmacy. The 24 volunteers are randomly divided into two groups and are divided into two stages of the study. This study is double-blind and the recipient and analyzer will not be in the process of consuming the product. Blood samples will be collected from each volunteer at specified times for 24 hours. The method used to measure the amount of drug in the samples of volunteers will be performed using high-performance liquid chromatography and an infrared detector.

Participants/Inclusion and exclusion criteria

Ages 18 to 45 years, Real weight (TBW) in the range of + -20% ideal weight, Non-smoker

Intervention groups

1. Enteric coated tablets of Pantoprazole formulated at Exir Pharmaceutical company 2. Enteric coated tablets of Pantoprazole formulated at Takeda company

Main outcome variables

Metformin plasma concentration; Area under the curve; Half-life time; Time to reach maximum plasma concentration; Maximum concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111107008022N8**

Registration date: **2022-01-28, 1400/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-28, 1400/11/08**

Update count: **0**

Registration date

2022-01-28, 1400/11/08

Registrant information

Name

Katayoun Derakhshandeh

Name of organization / entity

Hamadan University of Medical Sciences, Pharmacy school

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1590

Email address

kderakhshandeh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-28, 1400/11/08

Expected recruitment end date

2022-02-11, 1400/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of two different Pantoprazole 40mg formulations (Exir Pharmaceutical Company & reference) in 24 Iranian volunteers

Public title

Bioequivalency study of two different Pantoprazole formulations

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

24 healthy male and female volunteers will participate in this study Aged 18 to 45 years based on laboratory safety tests Paraclinical health based on tests performed No history of diseases affecting drug pharmacokinetic processes Lack of any chronic or acute medication at least 1 week before the start of the study Adherence to the criteria on the basis of moral obligation and signed an informed consent Actual weight (TBW) in the range of 20% IBW

Exclusion criteria:

Subject showed clinically relevant deviations from normal in physical examination. Subject had undergone surgery of the gastro-intestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last three months before the first treatment Subject had a history of alcohol abuse or smokes more than 10 cigarettes per day. Use any medication within 14 days before the first treatment. A history of allergic to biguanides

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each participant in each study period will receive a single dose of test and reference formulations

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 24 volunteers were randomly divided into two groups of 12 test (A) and reference (B) drug recipients by Excel software, then in the second phase, groups A and B will be cross-referenced to the test and drug recipients. Randomization method: First I create a Microsoft Excel worksheet, in column 1 I write the number of candidates (1 to 24). In the second column, we write the groups in which the samples are placed (reference and test). 12 The first sample as a reference

and the next 12 samples as a test sample. In column 3, we add the randomization formula (a function called RAND). Filter the contents of column 3 in ascending or descending order to make it random. Finally, the number of candidates is divided into two groups: reference and test.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this project, the volunteers, person responsible for blood sampling and analyzer are kept blind. To blind these people, all the information collected is coded to the researcher, and after the analysis is completed, codes will be opened.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committees of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Beside Mardom amusement Park, Shahid Fahmideh Blvd, Hamadan , Iran

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2022-01-21, 1400/11/01

Ethics committee reference number

IR.UMSHA.REC.1400.846

Health conditions studied

1

Description of health condition studied

Health volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

blood samples were collected at 0, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10 and 12 h following drug administration

Method of measurement

Using HPLC instrument

Secondary outcomes

1

Description

Pharmacokinetic parameters: Half-life, Cmax The peak plasma concentration of a drug after administration, The volume of distribution, and Clearance

Timepoint

0; 0.5; 1.0; 2.0; 3.0; 4.0; 4.5; 5.0; 5.5; 6.0; 6.5; 7.0; 8.0; 9.0; 10.0 and 12.0 hours post-dose

Method of measurement

Drug analysis in plasma using a chromatographic apparatus and calculating pharmacokinetic parameters using pharmacokinetic models

Intervention groups

1

Description

Intervention group: Oral administration of a single dose of 40 mg pantoprazole tablets made by Takeda company to 12 volunteers in two periods. The interval between two periods, called washout is the time when the drug is removed from the body and its duration is calculated as 5 to 7 half-lives of the drug.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Pharmacy, Hamadan University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Exir Pharmaceutical Company

Full name of responsible person

Mohsen Kordi

Street address

Borojerd, 2 Km of ring road

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Borojerd

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Lorestan

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69189

Phone

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Email

info@exir.co.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Exir Pharmaceutical 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

Hamedan University of Medical Sciences

Full name of responsible person

Katayoun Derakhshandeh

Position

Prof of Pharmaceutics

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

The pharmacokinetic data obtained from the study are for each volunteer in both the test and reference groups.

When the data will become available and for how long

6 months after the end of the study

To whom data/document is available

All researchers and clinical specialists

Under which criteria data/document could be used

There is no denial of access to data

From where data/document is obtainable

The results of the project are reported in the form of a published paper. Article will be available after it is published. If needs quicker access to the results, can reach us at "k.derakhshandeh@umsha.ac.ir"

What processes are involved for a request to access data/document

There will be no problem accessing results when publishing results in online articles. The wait time to access the results will be 3 months after the project is completed. If needs quicker access to the results, can reach us at "k.derakhshandeh@umsha.ac.ir".

Comments