# 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 entric 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)

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**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 and12.0 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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**Province**
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**Phone**
+98 66 4260 6022
**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**
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## Person responsible for updating data

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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**