# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparative bioequivalence study of the Dexlansoprazole 60 mg Delayed-release Tablets manufactured by Darman Yab Darou Pharmaceutical Company vs. Dexilant® Tablets manufactured by Takeda Pharma Pharmaceutical Company in healthy volunteers

## Protocol summary

**Study aim**
Examining the bioequivalency of domestically produced Dexlansoprazole 60 mg Delayed-release Tablets formulations with brand named ®Dexilant

**Design**
A crossover, not blinded, randomized, bioequivalence clinical trial on 24 healthy volunteers.

**Settings and conduct**
Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. The number of 24 volunteers in the age range of 18-55 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting, and blood is taken at 16 time points. One weeks later, the process is repeated for the brand medicine

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: the weight range of 60-100 kg; being a non-smoker; being healthy in terms of physical examination, ECG, and laboratory tests; and volunteers who have agreed to an informed consent form. Exclusion criteria: History of allergic or adverse reaction to Dexlansoprazole or any similar product; blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg; Individuals who have donated whole blood during the previous 2 months of the study or donated blood components within 2 weeks before taking the first dose of the drug.

**Intervention groups**
Intervention group 1:Dexlansoprazole 60 mg Delayed-release Tablets by Darman Yab Darou Pharmaceutical Company is the test product. Intervention group 2: Dexilant® Tablets manufactured by Takeda Pharma Pharmaceutical Company is the reference product. In each period, 12 of 24 subjects will be given a single dose of this product, and for up to 12 hours, 3 ml of blood will be collected from the volunteer at 16 time points each time. After the washout period, the volunteers are placed in the opposite group

**Main outcome variables**
Plasma concentration of the drug

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20130313012810N111**
Registration date: **2026-07-09, 1405/04/18**
Registration timing: **prospective**

Last update: **2026-07-09, 1405/04/18**
Update count: **0**

**Registration date**
2026-07-09, 1405/04/18

**Registrant information**

**Name**
Hamed Hamishehkar

**Name of organization / entity**
Drug Applied Research Center, Tabriz University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 41 1336 3311

**Email address**
hamishehkar.hamed@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2026-08-01, 1405/05/10

**Expected recruitment end date**

2026-08-06, 1405/05/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative bioequivalence study of the Dexlansoprazole 60 mg Delayed-release Tablets manufactured by Darman Yab Darou Pharmaceutical Company vs. Dexilant® Tablets manufactured by Takeda Pharma Pharmaceutical Company in healthy volunteers

**Public title**

Dexlansoprazole tablet bioequivalence

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers All candidates must be non-smokersCandidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose Volunteers who have agreed to an informed consent form. All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw

**Exclusion criteria:**

History of allergic or adverse reaction to Dexlansoprazole or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Individuals who have donated whole blood during the last 2 months from the study Individuals who have donated blood components within 2 weeks before taking the first dose of the drug.

**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**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To randomly assign people to two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1, and Group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period

**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 Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665811

**Approval date**

2026-06-22, 1405/04/01

**Ethics committee reference number**

IR.TBZMED.REC.1405.210

## Health conditions studied

### 1

**Description of health condition studied**

Bioequivalence study in healthy volunteers

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Plasma concentration of the drug

**Timepoint**

16 sampling time included pre-dose (time 0) and at the following hours post-dose: 0.5، 1، 1.5، 2، 2.5، 3، 3.5، 4، 4.5، 5، 6، 7، 8، 10 and 12h

**Method of measurement**
Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group 1: In this group, volunteers are given an oral dose of the Dexlansoprazole 60 mg Delayed-release Tablets manufactured by Darman Yab Darou Pharmaceutical Company. In each period, 12 of 24 subjects will be given an oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 2: In this group, volunteers are given an oral dose ofthe Dexlansoprazole 60 mg Delayed-release Tablets manufactured by Takeda Pharma Pharmaceutical Company. In each period, 12 of 24 subjects will be given an oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Drug Applied Research Center, Tabriz University of Medical Sciences
**Full name of responsible person**
Hamed Hamishehkar
**Street address**
Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
51656-65811
**Phone**
+98 41 3336 3311
**Email**
hamishehkar.hamed@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Darman Yab Darou Pharmaceutical Company
**Full name of responsible person**
پریسا منصوری
**Street address**
No. 36, corner of Azadegan, 20th street (Shahid Abtahi), Kurdistan highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1437634561
**Phone**
+98 21 87174
**Email**
drugsafety@darmanyab.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Darman Yab Darou 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**
Tabriz University of Medical Sciences
**Full name of responsible person**
Hamed Hamishehkar
**Position**
professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
**Street address**
Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**

51656-65811

**Phone**
+98 41 3336 3181

**Fax**
+98 41 3336 3311

**Email**
hamishehkar.hamed@gmail.com

**Web page address**
http://darc.tbzmed.ac.ir/

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
Hamed Hamishehkar

**Position**
professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Medical Pharmacy

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## Person responsible for updating data

**Contact**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
Hamed Hamishehkar

**Position**
professor

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**Web page address**
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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