# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparative bioequivalence study of the Linagliptin 5-mg Tablets manufactured by DarmanYab Darou Pharmaceutical Company with Linagliptin brand tablets (Tradjenta®) by Boehringer Ingelheim.

## Protocol summary

**Study aim**

Demonstration of bioequivalence of Linagliptin tablet 5 mg of DarmanYab Darou Co. with Tradjenta® tablet manufactured by Boehringer Ingelheim after single dose administration.

**Design**

Single dose, randomized and crossover bioequivalence study of Linagliptin tablet 5 mg by DarmanYab Darou Co. with Tradjenta® (Boehringer Ingelheim) in 24 healthy male volunteers in two groups.

**Settings and conduct**

Study place and the place for blood sample analysis are the Drug Applied Research Center affiliated to Tabriz University of Medical Science, respectively. 24 healthy male volunteers will receive one of the two 5 mg Linagliptin tablets test or reference in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 28 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 24, 36, 48, and 72 hours after dosing.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Healthy male subjects in the age range of 18-60 years and BMI (Body Mass Index) of 18-30. Exclusion criteria: Subjects with Blood Pressure ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Any evidence of impairment of renal, hepatic, cardiac, lung or gastrointestinal function or a history of tuberculosis, epilepsy, asthma, diabetes, psychosis or glaucoma and regular smoker.

**Intervention groups**

Intervention group 1: Linagliptin tablet 5 mg by DarmanYab Darou Co. is the test product. Intervention group 2: Tradjenta® (Boehringer Ingelheim) is the reference product. In each period, 12 of 24 subjects will be given single dose of this product. After the washout period, the volunteers are placed in the opposite group.

**Main outcome variables**

Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200407046981N37**
Registration date: **2022-08-02, 1401/05/11**
Registration timing: **prospective**

Last update: **2022-08-02, 1401/05/11**
Update count: **0**

**Registration date**

2022-08-02, 1401/05/11

**Registrant information**


**Name**

Fatima Molavi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2023-01-19, 1401/10/29

**Expected recruitment end date**

2023-02-18, 1401/11/29

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparative bioequivalence study of the Linagliptin 5-mg Tablets manufactured by DarmanYab Darou Pharmaceutical Company with Linagliptin brand tablets (Tradjenta®) by Boehringer Ingelheim.

**Public title**
Study of absorption and elimination rate of Linagliptin tablets 5 mg in comparison with Linagliptin brand tablets (Tradjenta®).
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
The weight limit of each volunteer should be between 60 and 100 kg. All volunteers must be non-smokers. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Candidates who have consented to the consent form.
**Exclusion criteria:**
Known hypersensitivity or idiosyncratic reaction to Linagliptin or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two weeks before dosing.
**Age**
From **18 years** old to **60 years** old
**Gender**
Male

**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 in 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 the 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 Science
**Street address**
Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science, Tabriz, Iran
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5166614766
**Approval date**
2022-07-10, 1401/04/19
**Ethics committee reference number**
IR.TBZMED.REC.1401.330

## Health conditions studied

### 1

**Description of health condition studied**
Bioequivalence study
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Peak Plasma Concentration (Cmax)
**Timepoint**
At 0 (before dosing), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 24, 36, 48 and 72 hour after dosing
**Method of measurement**
High-performance liquid chromatography—mass spectrometry (HPLC-MS-MS)

## Secondary outcomes

### 1

**Description**
AUC (Area Under the Concentration-Time Curve)
**Timepoint**
At 0 (before dosing), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 24, 36, 48 and 72 hour after dosing.
**Method of measurement**
Using non-compartmental model of Win-Nonlin

Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

## Intervention groups

### 1

**Description**
Intervention group 1: In this group, volunteers are given a single oral dose of Linagliptin tablet 5 mg produced by DarmanYab Darou Co. (Domestic). In each period, 12 of 24 subjects will be given single 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 a single oral dose of Linagliptin tablet 5 mg (Tradjenta®), produced by Boehringer Ingelheim Company (Brand). In each period, 12 of 24 subjects will be given single 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

**Full name of responsible person**
Hamed Hamishehkar

**Street address**
Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran

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Hamishehkar.hamed@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Darmanyab darou pharmaceutical company

**Full name of responsible person**
Parisa Mansouri

**Street address**
No. 36, 20th St, kordestan high way, Tehran, Iran

**City**
Tehran

**Province**
Tehran

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**Phone**
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**Fax**
+98 21 8714 5120

**Email**
info@darmanyab.com

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Darmanyab 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**
Fatima Molavi

**Position**
Non-Faculty Academic Position

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Pharmaceutics

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## Person responsible for scientific inquiries

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Professor

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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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**Position**
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**Latest degree**
Ph.D.

**Other areas of specialty/work**
Pharmaceutics

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
There is no further information

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available