

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 \leq 90/60 mm/Hg or BP \geq 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 (C_{max}); 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)

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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 \leq 90/60 mm/Hg or BP \geq 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

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Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Darmanyab darou pharmaceutical company

Full name of responsible person

Parisa Mansouri

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

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Email

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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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Position

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Latest degree

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Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

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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