

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative bioequivalence study of Linagliptin 5 mg Tablet of Actoverco. and Trajenta of Boehringer as reference in 24 healthy male under fasting.

#### Protocol summary

##### Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Linagliptin 5 mg Tablet formulation as a test product with Trajenta 5 mg Tablet formulation as a reference product and to evaluate the bioequivalence of these two formulations.

##### Design

Non-blinded, randomized, crossover in vivo bioequivalence study in 24 healthy males under fasting conditions. Block randomization for a treatment sequence of Test/Reference or Reference/Test is used.

##### Settings and conduct

During each study period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran).13 blood samples were collected during 72 hours post intervention. A 21-day washout interval separated to study periods.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) between 18.5 and 30 (inclusive), calculated as kg/m<sup>2</sup>. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Exclusion Criteria: Known hypersensitivity to linagliptin or inactive ingredients. Acute infection within one week preceding first study drug administration.

##### Intervention groups

Intervention group 1: Linagliptin 5 mg Tablet, produced by Actoverco. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Trajenta 5 mg Tablet, produced by Boehringer is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

##### Main outcome variables

Peak Plasma Concentration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180620040164N38**

Registration date: **2023-01-03, 1401/10/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-01-03, 1401/10/13**

Update count: **0**

##### Registration date

2023-01-03, 1401/10/13

##### Registrant information

##### Name

Behzad Montaha Sangari

##### Name of organization / entity

Noor research and educational institute (Tavan)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6600 7026

##### Email address

info@tavaninstitute.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-30, 1401/10/09

##### Expected recruitment end date

2023-01-13, 1401/10/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparative bioequivalence study of Linagliptin 5 mg Tablet of Actoverco. and Trajenta of Boehringer as reference in 24 healthy male under fasting.

### Public title

Comparative in vivo evaluation of 2 Linagliptin 5 mg Tablet formulations.

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Healthy subjects (male) between 18 - 45 years of age and Body Mass Index (BMI) between 18.5 and 30 (inclusive), calculated as kg/m<sup>2</sup>. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal vital signs. Subjects who agree with patient consent form.

#### Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to linagliptin or inactive ingredients. Acute infection within one week preceding first study drug administration. Subject has a history of severe diseases which have direct impact on the study. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who have used any drug including prescription or Over-The-Counter (OTC) drugs within 14 days prior to the start of the study and might need drug intake during study period. Subjects who have a history of alcohol or substance abuse within the last 5 years. Heavy drinker of alcohol, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. Subject intends to be hospitalized within 3 months after first study drug administration. Subjects who, through completion of this study, would have donated more than 500 ml of blood in 7 days.

### Age

From **18 years** old to **45 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

The randomization schedule will be generated with <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. A 2\*2 block randomization list is created. We have 12 blocks and within each two volunteer numbers (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.

### 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, School of Pharmacy, Nursing & Midwifery - Shahid Beheshti University of medical sciences

##### Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1996835113

#### Approval date

2022-10-25, 1401/08/03

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.127

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes mellitus

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

Peak Plasma Concentration (C<sub>max</sub>)

#### Timepoint

13 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 24, 48 and 72 hours after intervention.

#### Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

## Secondary outcomes

### 1

#### Description

AUC (Area Under the Concentration-Time Curve)

#### Timepoint

13 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, 24, 48 and 72 hours after intervention.

#### Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

## Intervention groups

### 1

#### Description

Intervention group 1: Linagliptin 5 mg Tablet , produced by Actoverco. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Trajenta 5 mg tablet, produced by Boehringer is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 21-day wash-out period the intervention 1 will be given to these subjects.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hakim Farabi Clinic

##### Full name of responsible person

Ebrahim Siahpoosh

##### Street address

No. 57, Shemshad alley, in front of Sallor town

##### City

Tehran

##### Province

Tehran

##### Postal code

4635314588

##### Phone

+98 21 9253 5647

##### Email

partochem@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Actover Pharmaceutical Co.

##### Full name of responsible person

Dr. Ramin Daneshmir

##### Street address

No. 58, 8th St., Gisha

##### City

Tehran

##### Province

Tehran

##### Postal code

No. 58, 8th St., Gis

##### Phone

+98 21 4162 7000

##### Email

info@actoverco.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Actover Pharmaceutical Co.

#### 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

Noor Research & Development Institute

##### Full name of responsible person

علی آقایی

##### Position

Master

##### Latest degree

Master

##### Other areas of specialty/work

Pharmacy

##### Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

##### City

Tehran

##### Province

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1459926609

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+98 21 6600 4027  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Principal investigator  
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Ph.D.  
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Medical Pharmacy  
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## Person responsible for updating data

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1459926609  
**Phone**  
+98 21 6600 4027  
**Email**  
partochem@gmail.com

## 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