# 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/m2. 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/m2. 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 (Cmax)

**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
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**Email**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Actover Pharmaceutical Co.
**Full name of responsible person**
Dr. Ramin Daneshmir
**Street address**
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**City**
Tehran
**Province**
Tehran
**Postal code**
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**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
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## Person responsible for scientific inquiries

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**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