

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparative bioequivalence study of Sitagliptin 100 mg tablet of Actoverco. and Januvia 100 mg tablet of Merck 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 Sitagliptine 100 mg tablet formulation as a test product with Januvia 100 mg 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 male under fasting condition.

##### Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran).17 blood samples were collected during 72 hours post intervention. A 7-day washout interval separated to study periods.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m<sup>2</sup>. Exclusion criteria: Hypersensitivity to the Dipeptidyl peptidase 4 inhibitors, investigational drug and/or inactive ingredients. Subjects who has used any drug including prescription or Over-The-Counter (OTC) within 14 days prior to the start of the study and might need drug intake during study period.

##### Intervention groups

Intervention group 1: Sitagliptin 100 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: Januvia 100 mg tablet , produced by Merck 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: **IRCT20180620040164N27**

Registration date: **2022-05-22, 1401/03/01**

Registration timing: **prospective**

Last update: **2022-05-22, 1401/03/01**

Update count: **0**

##### Registration date

2022-05-22, 1401/03/01

##### 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

2022-06-06, 1401/03/16

##### Expected recruitment end date

2022-06-21, 1401/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparative bioequivalence study of Sitagliptin 100 mg tablet of Actoverco. and Januvia 100 mg tablet of Merck as reference in 24 healthy male under fasting.

### Public title

Comparative in vivo evaluation of 2 Sitagliptin 100 mg Tablet formulations

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Healthy subjects (male) between 20-45 years of age. 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. Body Mass Index (BMI) within 15% of normal range 18.5 and 30 (inclusive), calculated as kg/m<sup>2</sup>.

#### Exclusion criteria:

Hypersensitivity to the DPP-4 inhibitors, investigational drug and/or to inactive constituents. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who has 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. History of alcohol or drug abuse within 2 years before the start of the study. Heavy drinker of caffeine, or caffeinated drinks. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study. Heavy drinker of grapefruit juice Subjects on special diet (such as vegetarians) Subjects who do exertional physical activity.

### Age

From **20 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's number (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 of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medica

##### Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1996835113

#### Approval date

2021-08-10, 1400/05/19

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.112

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes Mellitus

#### ICD-10 code

E11

#### ICD-10 code description

Type 2 diabetes mellitus

## Primary outcomes

### 1

#### Description

Peak Plasma Concentration (Cmax)

#### Timepoint

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 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

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 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: Sitagliptin 100 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: Januvia 100 mg tablet, produced by Merck is the reference 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 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

1446863914

##### 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

Ali Aghaei

##### Position

Master

##### Latest degree

Master

##### Other areas of specialty/work

Pharmacy

##### Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymouri Street, Tarasht

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##### Province

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1459926609

##### Phone

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tavan Institute

**Full name of responsible person**

Seyed Mohsen Foroutan

**Position**

Principal investigator

**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**

Tavan Institute

**Full name of responsible person**

Ali Aghaei

**Position**

Master

**Latest degree**

Master

**Other areas of specialty/work**

Pharmacy

**Street address**

Sharif innovation station, North Habibollah Street,  
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**City**

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**Province**

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**Postal code**

1459926609

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**Email**

partochem@gmail.com

## 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**

It's undetermined yet.

**Study Protocol**

Undecided - It is not yet known if there will be 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