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/m2. 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)

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Iran (Islamic Republic of)

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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/m2.

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

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4635314588

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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

No. 58, 8th St., Gisha

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Tehran

Province

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Postal code

1446863914

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+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

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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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
It's undetermind 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