

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Randomized, single-dose, crossover comparative bioequivalence study of Metformin/Sitagliptin 1000/50 mg of Actoverco. and Merck Shop & Dohme B.V. in 24 healthy male under fasting conditions

Protocol summary

Study aim

The aim of this study is to compare the pharmacokinetic parameters of Metformin 1000 mg + Sitagliptin 50 mg FDC tablet as a test with Janumet FDC tablet as the reference product and evaluation of bioequivalence between these two formulations.

Design

Randomized, single-dose, crossover bioequivalence study of Metformin 1000 mg + Sitagliptin 50 mg tablets of Actover Co. and Merck Shop & Dohme B.V. in 24 healthy male under fasting conditions.

Settings and conduct

This study will be conducted in two periods, with a 7-day interval between these 2. In the first period, 12 of 24 subjects will be given the test drug and the others reference. In the second period the alternative intervention will be taken by subjects.

Participants/Inclusion and exclusion criteria

Healthy male subjects 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. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations.

Intervention groups

Intervention group (test): one Metformin 1000 mg + Sitagliptin 50 mg FDC tablet, produced by Actover Co. as the test product. (Reference): One Janumet tablet, produced by Merck Shop & Dohme B.V as the reference product. During this study, volunteers will be given one of intervention sequences test/reference or reference/test according to randomization schedule.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N15**

Registration date: **2021-12-03, 1400/09/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-03, 1400/09/12**

Update count: **0**

Registration date

2021-12-03, 1400/09/12

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

2021-11-27, 1400/09/06

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, single-dose, crossover comparative bioequivalence study of Metformin/Sitagliptin 1000/50 mg of Actoverco. and Merck Shop & Dohme B.V. in 24 healthy male under fasting conditions

Public title

bioequivalence study of Metformin 100 mg + Sitagliptin 50 mg tablets in 24 healthy male under fasting conditions

Purpose

Treatment

Inclusion/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. 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:

Subjects with known allergy to the products tested. Subject with a history of neoplastic disease (cancer), stroke, chronic seizures or major neurological disorder, clinically significant endocrine, gastrointestinal, cardiovascular, hematological, hepatic, immunological, renal, respiratory, or genitourinary abnormalities or diseases. 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, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. 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.

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**

More than 1 sample in each individual

Number of samples in each individual: **28**

In each period, 14 blood samples are collected from each subject and this study includes 2 periods

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization schedule is generated with the BEAR

statistical software (Release V2.7.7). Each volunteer is randomly assigned to one of the 2 different sequence of treatments according to their entrance number to study which is allocated after screening.

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 Shahid Beheshti University of Medical Sciences

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2021-05-18, 1400/02/28

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.036

Health conditions studied

1

Description of health condition studied

Comparative safety and efficacy of the generic Actover Co. Metformin 1000mg + Sitagliptin 50 mg tablet versus brand Janumet Merck Shop & Dohme B.V tablet in healthy male volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (C_{max})

Timepoint

During 2 months 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

During 2 months 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 (test): Sitagliptin 50 mg + Metformin 1000 mg FDC tablet, produced by Actover is the test product. During 2 study periods, 12 subjects will be given this drug first and the others as the second intervention.

Category

Treatment - Drugs

2

Description

Intervention group (Reference): Janumet FDC tablet, produced by Merck Shop & Dohme B.V is the reference product. During 2 study periods, 12 subjects will be given this drug first and the others as the second intervention.

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, Sallor city

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4635314588

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Actover co

Full name of responsible person

Nahaleh Naraghi

Street address

No 58, 6th St, Balouchestan St, Tehran, Iran

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1459926609

Phone

+98 21 4163 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 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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Email

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

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Latest degree

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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 not specified 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