Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 comare 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)

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+98 21 6600 7026

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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 (Cmax)

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
Phone
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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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Province
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Postal code
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
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Person responsible for scientific inquiries

Contact

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Tavan Institute

Full name of responsible person
Seyed Mohsen Foroutan

Position
Principal investigator

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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 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