

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparative bioequivalence study of Empagliflozin 12.5 mg+ Metformin 1000 mg of ACTOVERCO and Boehringer Ingelheim Inc. in 24 healthy male under fasting

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Empagliflozin 12.5 mg + Metformin 1000 mg formulation as a test product with Synjardy® tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Empagliflozin 12.5 mg + Metformin 1000 mg F.C. tablet of Actover. and Boehringer Ingelheim. in 24 healthy male under fasting.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion 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. History of relevant diseases (gastrointestinal, hepatic, renal, respiratory, cardiovascular, metabolic, immunological or hormonal). Surgery of the gastrointestinal tract that could interfere with kinetics of the study drug(s).

Intervention groups

Intervention group (test): Empagliflozin 12.5 mg + Metformin 1000 mg F.C. tablet, produced by Actover is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): Synjardy® capsule, produced by Boehringer Ingelheim 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: **IRCT20180620040164N13**

Registration date: **2021-10-26, 1400/08/04**

Registration timing: **prospective**

Last update: **2021-10-26, 1400/08/04**

Update count: **0**

Registration date

2021-10-26, 1400/08/04

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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-13, 1400/08/22

Expected recruitment end date

2021-11-27, 1400/09/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Empagliflozin 12.5 mg+ Metformin 1000 mg of ACTOVERCO and Boehringer Ingelheim Inc. in 24 healthy male under fasting

Public title

Bioequivalence study of Empagliflozin 12.5 mg+ Metformin 1000 mg 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:

History of relevant diseases (gastrointestinal, hepatic, renal, respiratory, cardiovascular, metabolic, immunological or hormonal). History of surgery of the gastrointestinal tract that could interfere with kinetics of the study drug(s). Diseases of the central nervous system (such as epilepsy), other neurological disorders or psychiatric disorders. History of relevant orthostatic hypotension, fainting spells, or blackouts. Chronic or relevant acute infections. Hypersensitivity to the investigational drugs 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, 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.

AgeFrom **20 years** old to **45 years** old**Gender**

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample sizeTarget sample size: **26****Randomization (investigator's opinion)**

Randomized

Randomization description

The randomization schedule will be generated with <https://www.sealedenvelope.com/simple-randomiser/v1/lis>. 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 Shahid Beheshti University of Medical Sciences

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.141

Health conditions studied**1****Description of health condition studied**

Bioequivalence investigation of the generic Actover. Empagliflozin 12.5 mg + Metformin 1000 mg F.C. tablet with brand Synjardy® Boehringer Ingelheim tablet.

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: Intervention group: (test):
Empagliflozin 12.5 mg + Metformin 1000 mg F.C. tablet, produced by Actover is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: Empagliflozin 12.5 mg + Metformin 1000 mg F.C. tablet, produced by Boehringer Ingelheim is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Farabi Clinic
Full name of responsible person
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Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
ACtover Pharmaceutical Co
Full name of responsible person
Nahaleh Naraghi
Street address
58 plaque, 8th St., Gisha
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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
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Person responsible for updating data

Contact

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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