# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparative bioequivalence study of Empagliflozin 25mg tablet of Actoverco. and Boehringer.

## Protocol summary

**Study aim**

This study was performed to compare the pharmacokinetics and endotracheal parameters of the formulation of Empagliflozin 25 mg tablet of Actover Co. as a test product with the formulation of Jardiance 25 mg tablet of Boehringer as a reference product and evaluation of biological equivalence of these two formulations is done.

**Design**

Randomized, single-dose, crossover comparative bioequivalence study of Empagliflozin 25 mg of Actover Co. and Boehringer 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 known allergy to the products tested. Subjects with chronic or active gastrointestinal diseases such as esophageal diseases, gastritis, gastric ulcers, enteritis, active gastrointestinal bleeding or got any digestive tract surgery within three years. Subject with a history of circulatory system, endocrine system, nervous.

**Intervention groups**

Intervention group (test): Empagliflozin 25 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 (Reference): Jardiance 25 mg tablet, produced by Boehringer 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: **IRCT20180620040164N19**
Registration date: **2022-01-19, 1400/10/29**
Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**
Update count: **0**

**Registration date**

2022-01-19, 1400/10/29

**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**

2022-01-22, 1400/11/02

**Expected recruitment end date**

2022-02-09, 1400/11/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative bioequivalence study of Empagliflozin 25mg tablet of Actoverco. and Boehringer.

**Public title**

Bioequivalence study of Empagliflozin 25 mg tablet 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. Subjects with chronic or active gastrointestinal diseases such as esophageal diseases, gastritis, gastric ulcers, enteritis, active gastrointestinal bleeding or got any digestive tract surgery within three years. Subject with a history of circulatory system, endocrine system, nervous system, digestive system, respiratory system, hematology, immunology, psychiatry, and metabolic abnormalities. Those who have undergone surgery during the first four weeks before the trial or are scheduled to perform surgery during the study period. 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**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization schedule will be generated with the BEAR statistical software (Release V2.7.7). Each volunteer will be randomly assigned to one of the 2 different sequence of treatments according to the order of entering the study which will be 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**

1996835113

**Approval date**

2021-08-10, 1400/05/19

**Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1400.118

## Health conditions studied

### 1

**Description of health condition studied**

Bioequivalence investigation of the generic Actoverco. Empagliflozin 25 mg tablet with brand Jardiance 25 mg tablet Boehringer.

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

En 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): Empagliflozin 25 mg Tablet, produced by Actoverco. and Food Supplement Co. 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: (reference):Jardiance 25 mg Tablet, produced by Boehringer is the reference 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**
Ebrahim Siahpoosh
**Street address**
No. 57, Shemshad alley, Sallor city
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mina.hasanabadi@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Actover Pharmaceutical Co.
**Full name of responsible person**
Reza karimi mostofi
**Street address**
58 plaque, 8th St., Gisha
**City**
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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**
Master
**Latest degree**
Master
**Other areas of specialty/work**
pharmacy
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## Person responsible for scientific inquiries

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**Position**
Principal investigator

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Ph.D.

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Medical Pharmacy

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## Person responsible for updating data

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**Position**
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**Latest degree**
Master

**Other areas of specialty/work**
pharmacy

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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