Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Randomized, single-dose, crossover comparative bioequivalence study of Eplerenone 50 mg tablet of ACTOVERCO and Pfizer Inc. in 24 healthy male under fasting conditions

Protocol summary

Study aim

This study was performed to compare the pharmacokinetics and invivo parameters of Eplerenone 50 mg formulation as a test product with Inspra® tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Eplerenone 50 mg tablets of Actover. and Pfizer. in 24 healthy male under fasting.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). 2 dosing periods will be separated by a 7-day washout period.

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. Subjects with normal vital signs. Exclusion Crieteria: Subject has a history of significant renal disorder (impaired renal function), hepatic disorder (impaired hepatic function), cardiovascular disorder. Subjects with known allergy to the products tested.

Intervention groups

Intervention group (test):Eplerenone 50 mg tablet, produced by Actover. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. Intervention group (Reference): Inspra® tablet, produced by Pfizer is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N56**
Registration date: **2024-02-21, 1402/12/02**
Registration timing: **prospective**

Last update: **2024-02-21, 1402/12/02**
Update count: **0**

Registration date

2024-02-21, 1402/12/02

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

2024-04-02, 1403/01/14

Expected recruitment end date

2024-04-16, 1403/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Randomized, single-dose, crossover comparative bioequivalence study of Eplerenone 50 mg tablet of ACTOVERCO and Pfizer Inc. in 24 healthy male under fasting conditions

Public title
bioequivalence study of Eplerenone 50 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:
Subject has a history of significant renal disorder (impaired renal function), hepatic disorder (impaired hepatic function), cardiovascular disorder. Subjects with known allergy to the products tested. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. 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 **18 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 numbers (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.1400.140

Health conditions studied

1

Description of health condition studied
Heart failure

ICD-10 code
I50

ICD-10 code description
Heart failure

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):Eplerenone 50 mg 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(Reference): Inspra® tablet, produced by Pfizer 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
Noor Research & Development Institute (Tavan)
Full name of responsible person
Ali Aghaei
Street address
Sharif Innovation Station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
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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
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
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Person responsible for scientific inquiries

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Seyed Mohsen Foroutan
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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