Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

In- Vivo Bioequivalence study of Eplerenone tablet 50mg Anourayhan (Alderon 50mg) with brand drugs (Inspra 50mg, Pfizer, Gremany) in Iranian healthy volunteers

Protocol summary

Study aim
In- Vivo Bioequivalence study of Eplerenone tablet 50mg Abourayhan (Alderon 50mg) with brand drugs (Inspra 50mg, Pfizer, Gremany).

Design
Single dose, randomized, two sequences, two period crossover with a washout period.

Settings and conduct
This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four hours.The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form.In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria
24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis functions with both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-25 respectively.

Intervention groups
Both groups received in cross-over design medication and testing at two different cross-sections and Therefor,the test results are independent of individual differences and it will only show the difference in the formulation of the two drugs.

Main outcome variables
Cmax,Tmax, T1/2, Ke (Elemination)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046010N2**
Registration date: **2020-06-09, 1399/03/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-09, 1399/03/20**
Update count: **0**

Registration date
2020-06-09, 1399/03/20

Registrant information

Name
Javad Shokri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3661 4125

Email address
shokri.j@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-25, 1399/03/05

Expected recruitment end date
2020-11-25, 1399/09/05

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In- Vivo Bioequivalence study of Eplerenone tablet 50mg Anourayhan (Alderon 50mg) with brand drugs (Inspra 50mg, Pfizer, Gremany) in Iranian healthy volunteers

Public title

Eplerenone tablet 50mg Abourayhan (Alderon 50mg),In-Vivo Bioequivalence in iranian healthy volunteer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health(liver, heart, kidney) Body mass index(18-28) Informed consent Age(18-60)

Exclusion criteria:

Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

People in different age groups are invited to cooperate through the advertisement.Then people are selected. Individuals will be randomly selected through advertisements. The number of individuals will be randomly selected and the first twelve will be selected as the first sequence and the second twelve will be selected as the second sequence.

Blinding (investigator's opinion)

Single blinded

Blinding description

Candidates are not aware of the test drug or brand name.

Placebo

Not used

Assignment

Crossover

Other design features

Tow period / Tow sequence with a washout time

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

No.48,Ferdows street, Ferdowsi Sq.

City

Tabriz

Province

East Azarbaijan

Postal code

51678744

Approval date

2019-12-23, 1398/10/02

Ethics committee reference number

IR.TBZMED.REC.1398.1044

Health conditions studied

1

Description of health condition studied

In this study the bioequivalence of test and brand of Esmoprazole will evaluated.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug analysis in plasma or whole blood

Timepoint

After blood sampling

Method of measurement

HPLC,LC-MS/MS or UPLC-MS/MS

Secondary outcomes

empty

Intervention groups

1

Description

Single dose of Eplerenone 50 mg tablet by (INSPRA® 50mg. Pfizer, Germany)Pharmaceutical Company as a reference product.

Category

Treatment - Drugs

2

Description

Single dose of 50 mg Eplerenone tablet by Abu Reihan Pharmaceutical Company as a test product.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Simin Baspar Teyf Gostar Company

Full name of responsible person
Javad Shokri

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No.48,Ferdos Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Aburayhan Pharmaceutical Co.

Full name of responsible person
Cobra moosavi, Pharm D.

Street address
Tehranpars intersection, Khoshvaght St. No. 1, Po.Box 16765/1568, Postal Cod: 1654613111

City
Tehran

Province
Tehran

Postal code
1654613111

Phone
+98 21 7770 7173

Fax
+98 21 7770 2066

Email
info@aburaihan.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Aburayhan 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
Tabriz University of Medical Sciences

Full name of responsible person
Javad Shokri

Position
Professor

Latest degree
Ph.D.

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
These date are as secure between researcher and related industries.
Study Protocol
No - There is not 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
Yes - There is a plan to make this available
Title and more details about the data/document
Only protocol and methods of study are sharable.
When the data will become available and for how long
After finishing of the protocol (Probably 6 months receiving IRCT code)
To whom data/document is available
Pharmaceutical and medical sciences researchers.
Under which criteria data/document could be used
Projects information's for any publications is not allowed.
From where data/document is obtainable
Contact with E-mail of the main researcher.
What processes are involved for a request to access data/document
Personal and academic details and the aim of the request.
Comments