Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Bioequivalence Study of amlodipine valsartan 10/160 mg manufactured by Alborz Darou and Exforge manufactured by Novartis in 24 Healthy Volunteers

Protocol summary

Study aim

The bioequivalence study of amlodipin- valsartan tablet manufactured by Alborz Darou company and Exforge tablet manufactured by Novartis company.

Design

Bioequivalence study, cross over, single blinded, randomized on 24 healthy volunteers, for randomization the rand function of excel was used.

Settings and conduct

Sampling of volunteers is done in Khorazmi Plasma Center in Islamshar. On the day of sampling, one 10/160 mg tablets of Amlodipine- valsartan manufactured by Alborz Darou or Novartis on two occasions and with a washout period of 14 days, will be administered orally with 240 ml of water to the volunteer. For example, if in the first period of administration, he received the Alborz Darou drug, he will receive Exforge, two weeks later. In each phase, 5 cc of blood sample will be taken at 0.5، 1، 1.5، 2، 2.5، 3، 3.5، 4، 4.5، 6، 8، 10، 12، 24, 32 hours after prescribing the medicine . Three weeks after the start of the study, the volunteer's cooperation in this research ends. The way to cooperate in these three weeks is that the drug is prescribed in the first day and after that 32 hours blood sampling is done at the mentioned times after washout period of two weeks the other drug is administered and blood samples will be taken at the same time

Participants/Inclusion and exclusion criteria

Healthy volunteers, in the age range of 18 to 55 years with a body mass index between 18 and 27 kg per square meter of the body, volunteers who are willing to comply with the requirements of the protocol and provide written informed consent. Exclusion citeria is smokers or smokers who smoke more than 10 cigarettes per day.

Intervention groups

The first group: 12 people who take Alborz Darou tablets.

The second group: 12 people who take Novartis tablets on the same day.

Main outcome variables

Plasma concentration and area under the curve of plasma concentration time of test and reference drug

General information

Reason for update

Acronym

هم ارزی زیستی

IRCT registration information

IRCT registration number: **IRCT20220209053979N5**
Registration date: **2023-02-04, 1401/11/15**
Registration timing: **prospective**

Last update: **2023-02-04, 1401/11/15**
Update count: **0**

Registration date

2023-02-04, 1401/11/15

Registrant information

Name

Roya Talari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8880 0892

Email address

talari_r@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-23, 1401/12/04

Expected recruitment end date

2023-03-09, 1401/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence Study of amlodipine valsartan 10/160 mg manufactured by Alborz Darou and Exforge manufactured by Novartis in 24 Healthy Volunteers

Public title

Bioeqivalence study of amlodipine valsartan 10/160 mg tablet

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Laboratory tests +/- 10% of normal interval without any history of chronic sickness

Exclusion criteria:

Systolic blood pressure less than 90 and diastolic less than 60 mm Hg Smoking more than 10 cigarette per day

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **16**

At times 0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 6, 8, 10, 12, 24 and 32 hours after drug administration, 5 ml of blood is taken from each volunteer.

Randomization (investigator's opinion)

Randomized

Randomization description

Using the rand option of the Excel software, the candidates are divided into two groups, and half of them will receive numbers 1-12 and the test drug, and the other half will receive numbers 13-24 and will receive the reference drug.

Blinding (investigator's opinion)

Single blinded

Blinding description

The tablets of Alborz Daru and Novartis are both oval shaped and pink in color, so the candidate does not know which company's drug he will receive in each phase of the study. On the other hand, the tubes of the volunteers' samples are also coded, so the analyzer does not know which company's drug he is analyzing, so only the researcher and the prescriber know which company's drug is being prescribed.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Science

Street address

Tehran University of Medical Science, 16 Azar St.,

City

Tehran

Province

Tehran

Postal code

1417713135

Approval date

2023-01-30, 1401/11/10

Ethics committee reference number

IR. TUMS. TIPS. REC. 1401. 106

Health conditions studied

1

Description of health condition studied

Bioequivalence study

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration time profile,

Timepoint

0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 6, 8, 10, 12, 24 and 32 hours after drug administration

Method of measurement

Liquid chromatography with mass spectrophotometry

Secondary outcomes

1

Description

Calculation of pharmacokinetic parameters like Cmax, AUC of test and reference drug.

Timepoint

0, 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 6, 8, 10, 12, 24 and 32 hours after drug administration

Method of measurement
Pharmacokientic parameters are calculated by excel.

Intervention groups

1

Description
Intervention group: 1 oral administration of one amlodipine valsartan 10/160 mg tablet manufactured by Alborz Daru Company to 12 healthy volunteers in fasting state with 240 ml of water. Then 16 blood samples are taken from the volunteers at certain intervals. In the second phase (two weeks later) this process is repeated in reverse. This means that these people take Novartis medicine and give blood samples at 16 time points
Category
Treatment - Drugs

2

Description
Intervention group 2: Oral administration of a 160/10 amlodipine valsartan tablet manufactured by Novartis to 12 healthy volunteers in fasting state with 240 ml of water. Then 16 blood samples are taken from the volunteers at certain intervals. In the second phase (two weeks later) this process is repeated in reverse. This means that these people take Alborz Daru's medicine and give blood samples at 16 time points
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kharazmi plasma center
Full name of responsible person
Sara Solgi
Street address
No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,
City
Islamshahr
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3313679886
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+98 21 5637 8236
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Info@kpcir.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz Darou
Full name of responsible person
Delara Vahidi
Street address
5th floor, No. 3, Navak Alley, Jahan Koodak cross ,Afrika Blvd.
City
Tehran
Province
Tehran
Postal code
1518646177
Phone
+98 21 8819 2773
Email
info@alborzdarouco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz Darou
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
Kharazmi Plasma Center
Full name of responsible person
Roya Talari
Position
Executer
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,
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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
The bioequivalence study data is completely confidential and according to the contract with Alborz Daru Company, it should not be published anywhere.
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
No - There is not a plan to make this available