

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 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 amlodipine- 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 criteria 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**  
Bioequivalence 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

Pharmacokinetic 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 Darou 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 Darou'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

##### Province

Tehran

##### Postal code

3313679886

##### Phone

+98 21 5669 4726

##### Fax

+98 21 5637 8236

##### Email

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

##### Street address

No. 13, Shehamat 1st Alley, Ali Ibn Abitalib St., Namaz Square,

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**Email**  
talari\_r@yahoo.com

## Person responsible for scientific inquiries

### Contact

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Kharazmi Plasma Center

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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**

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