

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### A cross over bioequivalence study of losartan H 50/12.5 mg tablet compared to Hyzaar 50/12.5 mg tablet manufactured by Merck in 24 healthy volunteers under fasting condition

#### Protocol summary

##### Study aim

to compare plasma concentration of losartan hydrochlorothiazide tab manufactured by Alborz Darou versus Hyzaar manufactured by Merck

##### Design

A randomized, double blind, single-dose, crossover study is conducted to compare the pharmacokinetic of losartan-hydrochlorothiazide 50/12.5 mg Alborz Darou (test) and Hyzaar® tablet manufactured by Merck in 24 healthy adults volunteers under fasting condition. For randomization, volunteers are divided into two groups using the RAND function of Excel software, and they are coded. Depending on the code, they receive one of the test and reference drugs

##### Settings and conduct

One day before the study, the test and reference tablets, which are completely similar in appearance, are packed in a disposable container. Volunteers come to the Khorazmi plasma center in Islamshahr, A single dose of one tablet of test or reference drug is administered to volunteers with 240 ml water and blood samples are taken at specified time, and then samples are transferred to the -20 freezer. Since samples are coded, the analyzer does not know which sample is analysed. so this study is double blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Healthy adult non-smokers subjects, 2. Between 18 to 45 years 3. Blood pressure more than 110/70 mmHg. exclusion Criteria: 1. history of any heart, renal, GI diseases 2. consumption of any medication within 1 month prior to the study 3. participation in any other clinical study in the past 3 months

##### Intervention groups

First intervention group: A single tablet of losartan hydrochlorothiazide manufactured by Alborz Darou company to 12 subjects. Second intervention group: A single dose of Hyzaar manufactured by Merck company

to 12 subjects. in the next week it is vise verse.

##### Main outcome variables

Drug plasma concentration; Area under the plasma concentration-time curve

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220209053979N2**

Registration date: **2022-07-07, 1401/04/16**

Registration timing: **retrospective**

Last update: **2022-07-07, 1401/04/16**

Update count: **0**

##### Registration date

2022-07-07, 1401/04/16

##### 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

2022-06-30, 1401/04/09

##### Expected recruitment end date

2022-07-07, 1401/04/16

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
A cross over bioequivalence study of losartan H 50/12.5 mg tablet compared to Hyzaar 50/12.5 mg tablet manufactured by Merck in 24 healthy volunteers under fasting condition

**Public title**  
A bioequivalence study of losartan H 50/12.5 mg tablet compared to Hyzaar 50/12.5 mg tablet manufactured by Merck in 24 healthy volunteers under fasting condition

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Sex: male. Age: 18 - 55 years. . BMI of 18-27 kg/m<sup>2</sup> with minimum of 50 kg weight. Volunteer willing to adhere to the protocol requirements and to provide written informed consent Non-smokers or smoker who smokes less than 10 cigarettes per day  
**Exclusion criteria:**  
Clinically relevant abnormalities in the results of the laboratory screening evaluation. Systolic blood pressure less than 100 mm Hg or more than 140 mm Hg and diastolic blood pressure less than 60 mm Hg or more than 90 mm Hg. Pulse rate less than 50/minute or more than 100/minute. History of allergy to the test drug or any drug chemically similar to the drug under investigation. History of consumption of prescribed medication since last 14 days or OTC medication since last 07 days before beginning of the study

**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**  
6 ml blood samples

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Since both Alborz Daru and the reference tablets are manufactured in the same size and white color , it is possible to make blinded. The drug (test drug or reference drug) is packed in small disposable containers a day before the study, Therefore, the volunteer does not

know which drug he is taking. Each volunteer is also assigned a code that the analyzer does not know which drug the volunteer received in each phase of the study.

**Placebo**  
Not used

**Assignment**  
Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

The Institute of Pharmaceutical Sciences -Tehran  
University of Medical Sciences

##### Street address

Tehran University of medical science, 16 Azar St.,  
Tehran , Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۱۹۷۳۳۱۴۱

#### Approval date

2022-06-21, 1401/03/31

#### Ethics committee reference number

IR.TUMS.TIPS.REC.1401.021

## Health conditions studied

### 1

#### Description of health condition studied

Blood concentration of test and reference drug is compared

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The plasma concentrations of the test and reference drugs is compared. A total of 16 blood samples are taken from each volunteer at different times

#### Timepoint

, 0.33, 0.66, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 , 24 , 36 hours after drug administration

#### Method of measurement

liquid chromatography mass spectrometry (LCMSMS)

## Secondary outcomes

## 1

### Description

Plasma concentration of the drug and consequently y pharmacokinetic parameters such as maximum plasma concentration and area under curve of the concentration-time profile of test and reference drug

### Timepoint

, 0.33, 0.66, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10 , 24 , 36 hours after drug administration

### Method of measurement

Plasma concentration of the drug is analyzed by liquid chromatography with mass detector

## Intervention groups

## 1

### Description

Intervention group: Oral administration of a single dose of 1 tablet of losartan H 50/12.5 mg of Alborz Darou to 12 healthy volunteers under fasting condition with 240 ml water, then 15 blood samples are taken from each volunteer at specified times. In the second phase, this group will received the losartan H 50/12.5 mg of Merck and 15 blood samples are taken from them.

### Category

Treatment - Drugs

## 2

### Description

Intervention group: Oral administration of a single dose of 1 tablet of losartan H 50/12.5 mg of Merck to 12 healthy volunteers under fasting condition with 240 ml water, then 15 blood samples are taken from each volunteer at specified times. In the second phase, this group will received the losartan H 50/12.5 mg of Alborz Darou and 15 blood samples are taken from them.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Kharazmi Plasma Center (Islamshahr)

#### Full name of responsible person

Sara Solgi

#### Street address

No. 13, Shahamat 1 Alley, Ali Ibn Abitaleb St., Namaz Square, Islamshahr, Tehran

#### 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

No. 3 , Navak St., Jahan kudak Intersection, Afrigha BLV, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1518646177

#### Phone

+98 21 8819 2773

#### Email

info@alborzdarouco.com

#### Grant name

The cost is provided by Alborz Darou

#### 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

executor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

No.13, First Shahamat Alley, Ali Ibn Abitaleb Street,

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talari\_r@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

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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 study is confidential and it is not possible to publish the data without the permission of the manufacturer

**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