

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/m² 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

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Islamshahr

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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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Email

talari_r@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kharazmi Plasma Center

Full name of responsible person

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Position

executor

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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 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