Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparative bioequivalence study of Losar H® 50/12.5 mg of Razak and MSD in 24 healthy male under fasting

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and invivo parameters of Losartan / Hydrochlorothiazide 50/12.5 mg formulation as a test product with HYZAAR® tablet formulation as a reference product and to evaluate the biocompatibility of these two formulations.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Losartan / Hydrochlorothiazide 50/12.5 mg tablet of Razak. and MSD. in 24 healthy male under fasting.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Noor Research and Development Institute (Tarasht, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Exclusion Criteria: Known hypersensitivity to losartan, hydrochlorothiazide, or any other components of the FDC tablet. 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.

Intervention groups

Intervention group (test): Losartan / Hydrochlorothiazide 50/12.5 mg tablet , produced by Razak is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): HYZAAR® Tablet, produced by MSD is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N47**
Registration date: **2023-07-17, 1402/04/26**
Registration timing: **prospective**

Last update: **2023-07-17, 1402/04/26**
Update count: **0**

Registration date

2023-07-17, 1402/04/26

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

Phone

+98 21 6600 7026

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-02, 1402/06/11

Expected recruitment end date

2023-09-16, 1402/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative bioequivalence study of Losar H® 50/12.5 mg of Razak and MSD in 24 healthy male under fasting

Public title
Bioequivalence study of Losar H® 50/12.5 mg in 24 healthy male under fasting conditions

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy subjects (male) between 18 – 45 years of age and Body Mass Index (BMI) between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:
Known hypersensitivity to losartan, hydrochlorothiazide, or any other components of the FDC tablet. 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. Oral temperature less than 95°P or more than 98.6°P. Respiratory rate less than 12/minute or more than 20/minute. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Subjects who have used any drug including prescription or Over-The-Counter (OTC) drugs within 14 days prior to the start of the study and might need drug intake during study period. Subjects who have a history of alcohol or substance abuse within the last 5 years. Heavy drinker of alcohol, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. Subject intends to be hospitalized within 3 months after first study drug administration. Subjects who, through completion of this study, would have donated more than 500 ml of blood in 7 days.

Age
From **18 years** old to **45 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer's number (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1996835113

Approval date
2023-05-23, 1402/03/02

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1402.030

Health conditions studied

1

Description of health condition studied
Secondary hypertension

ICD-10 code
I15

ICD-10 code description
Secondary hypertension

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
20 blood samples will be withdrawn pre-dose and at 0.25, 0.5, 0.75, 1, 1.33, 1.66, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24 and 48 hours after intervention.

Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
20 blood samples will be withdrawn pre-dose and at 0.25, 0.5, 0.75, 1, 1.33, 1.66, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24 and 48 hours after intervention.
Method of measurement
Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group1: Losar/ H 50/ 12.5 mg tablet , produced by Razak. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.
Category
Treatment - Drugs

2

Description
Intervention group2: HYZAAR® 50/12.5 Tablet, produced by MSD is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Research & Development Institut(Tavan)
Full name of responsible person
Ali aghaei
Street address
Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.
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Email
info@tavaninstitute.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Razak Pharmaceutical Co.
Full name of responsible person
Dr. Aazam sadat emami
Street address
Km 10,Lashgari Expy, Tehran-IRAN
City
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Province
Tehran
Postal code
1389736615
Phone
+98 21 4452 5413
Email
info@razakpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Razak 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
Noor Research & Development Institute
Full name of responsible person
Ali aghaei
Position
Master
Latest degree
Master
Other areas of specialty/work
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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
It's undetermind yet.
Study Protocol
Undecided - It is not yet known if there will be 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