

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Comparative bioequivalence study of Amlodipine 10/Valsartan 160 Tablet of Karen Pharma and Food Supplement Co. and EXFORGE® of Novartis as reference in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and in vivo parameters of Amlodipine 10/Valsartan 160 mg Tablet formulation as a test product with Exforge 10/160 mg Tablet formulation as a reference product to evaluate the bioequivalence.

Design

Non blinded, randomized, crossover in vivo bioequivalence study in 24 healthy male under fasting condition. Block randomization for a treatment sequence of Test/Reference or Reference/Test will be used.

Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran) according to a prepared block randomization schedule without blinding. 16 blood samples were collected during 72 hours post intervention. A 14-day washout interval separated 2 study periods.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy male subjects between 20 – 45 years of age and Body Mass Index (BMI) within 15% of the accepted values between 18.5 and 30 (inclusive), calculated as kg/m². Subjects with no significant diseases or clinically significant abnormal findings during clinical examination and laboratory evaluations. Exclusion Criteria: Subjects with known allergy to the products tested. Acute infection within one week preceding first study drug administration.

Intervention groups

Intervention group 1: amlodipine 10/Valsartan 160 mg Tablet, produced by Karen is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. After 14-day wash-out period the intervention 2 will be given to these subjects. Intervention group 2: Exforge 10/160 mg Tablet, produced by Novartis is the reference product. In each period, 12 of 24 subjects will be given a single oral dose

of this product. After 14-day wash-out period the intervention 1 will be given to these subjects.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N36**

Registration date: **2022-11-21, 1401/08/30**

Registration timing: **prospective**

Last update: **2022-11-21, 1401/08/30**

Update count: **0**

Registration date

2022-11-21, 1401/08/30

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

2022-11-22, 1401/09/01

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Amlodipine10/Valsartan160 Tablet of Karen Pharma and Food Supplement Co. and EXFORGE® of Novartis as reference in 24 healthy male under fasting.

Public title

Comparative in vivo evaluation of 2 Amlodipine 10/Valsartan160 mg Tablet formulations.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range (kg/m²) 18.5 and 30. 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:

Subjects with known allergy to the products tested. Acute infection within one week preceding first study drug administration. Hypotension (systolic blood pressure ≤100 mmHg or diastolic blood pressure ≤65 mmHg) or hypertension (systolic blood pressure ≥150mmHg or diastolic blood pressure ≥100 mmHg) Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period; Subjects who has 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; History of alcohol or drug abuse; Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity; A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study

Age

From **20 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 School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medica

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2022-10-25, 1401/08/03

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.128

Health conditions studied**1****Description of health condition studied**

Essential (primary) hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes**1****Description**

Peak Plasma Concentration (C_{max})

Timepoint

Before intervention and then at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 24, 48 and 72 hours post intervention in each period

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

Before intervention and then at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 10, 12, 24, 48 & 72 hours post intervention in each period

Method of measurement

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

Intervention groups

1

Description

Intervention group 1: Amlodipine 10 mg + Valsartan 160 mg tablet, produced by Karen is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-day wash-out period the intervention 2 will be given to these subjects.

Category

Treatment - Drugs

2

Description

Intervention group 2: Amlodipine 10 mg + Valsartan 160 mg tablet produced by NOVARTIS is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 14-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

Hakim Farabi Clinic

Full name of responsible person

Ebrahim Siahpoosh

Street address

No. 57, Shemshad alley, Sallor city

City

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Province

Tehran

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4635314588

Phone

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Email

partochem@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karen Pharma and Food Supplement Co.

Full name of responsible person

Zahra Mortazavi

Street address

No: 3, Western Nahid st. Africa Blvd.

City

Tehran

Province

Tehran

Postal code

۱۴۵۹۹۶۵۲۰۴

Phone

+98 21 2620 4283

Email

info@karenpharma.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Karen Pharma and Food Supplement 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

Pharmacy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
Tavan 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 not specified 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