Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

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.

Protocol summary

Study aim
This study will be performed to compare the pharmacokinetics and invivo 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 1will 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
info@tavaninstitute.ir

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 (Cmax)
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 1will 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
Tehran
Province
Tehran
Postal code
4635314588
Phone
+98 21 9253 5647
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
Street address
Sharif innovation station, North Habibollah, Hosseini Squ., Teymoury St., Tarasht
City
Tehran
Province
Tehran
Postal code
1459926609

Phone
+98 21 6600 4027
Email
info@tavaninstitute.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tavan Institute
Full name of responsible person
Seyed Mohsen Foroutan
Position
Principal investigator
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Sharif innovation station, North Habibollah, Hosseini Squ., Teymoury St., Tarasht
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 4027
Email
info@tavaninstitute.ir

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
Pharmacy
Street address
Sharif innovation station, North Habibollah, Hosseini Squ., Teymoury St., Tarasht.
City
Tehran
Province
Tehran
Postal code
1459926609
Phone
+98 21 6600 4027
Email
info@tavaninstitute.ir

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