Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparative bioequivalence study of Valsartan 160 mg tablet of Karen Pharma and Food Supplement Co. and Novartis pharmaceuticals.

Protocol summary

Study aim

This study was performed to compare the pharmacokinetics and endotracheal parameters of the formulation of Valsartan 160 mg tablet of Karen Company as a test product with the formulation of Diovan® 160 mg tablet of Novartis as a reference product and evaluation of biological equivalence of these two formulations is done.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Valsartan 160 mg of Karen Pharma and Food Supplement Co. and Novartis in 24 healthy male under fasting.

Settings and conduct

In each period, volunteers will receive a single dose of the treatment in the Farabi Clinic (Eslamshahr, Tehran). 2 dosing periods will be separated by a 7-day washout period.

Participants/Inclusion and exclusion criteria

Healthy candidates should be between 18-40 years old and their BMI should be in the range (Kg/m2) 18.5-30. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. History of known allergies to valsartan, new drugs or any of the inactive components of the formulation. A history of liver or gastrointestinal disease that may interfere with the absorption, distribution, metabolism, or excretion of the drug. History of liver or kidney disease.

Intervention groups

Intervention group (test): Valsartan 160 mg Tablet, produced by Karen Pharma and Food Supplement Co. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group (Reference): Valsartan 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.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N18**
Registration date: **2022-01-08, 1400/10/18**
Registration timing: **prospective**

Last update: **2022-01-08, 1400/10/18**
Update count: **0**

Registration date

2022-01-08, 1400/10/18

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

2022-01-20, 1400/10/30

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative bioequivalence study of Valsartan 160 mg tablet of Karen Pharma and Food Supplement Co. and Novartis pharmaceuticals.

Public title
Bioequivalence study of Valsartan 160 mg tablet in 24 healthy male under fasting conditions

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy candidates should be between 18-40 years old and their BMI should be in the range (Kg/m2) 18.5-30. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects must have normal vital signs. Sitting systolic blood pressure is in the range of 110-120 mm Hg and diastolic blood pressure is in the range of 70-80 mm Hg and heart rate is 60-90 beats per minute. Subjects who agree with patient consent form.

Exclusion criteria:
History of known allergies to valsartan, new drugs or any of the inactive components of the formulation; A history of liver or gastrointestinal disease that may interfere with the absorption, distribution, metabolism, or excretion of the drug; History of liver or kidney disease Smokers who smoke more than 10 cigarettes a day and have trouble not smoking during each clinical study period. History of anaphylaxis or angioedema History of bleeding or coagulation problems People who have taken over-the-counter or prescription drugs 7 days before the start of the first period will need to take the drug at the same time during the study. People with a history of alcohol or drug addiction Subjects who consume heavy caffeinated beverages, fruit juices (grapefruit juice) either follow a special diet (vegetarian) or do strenuous physical activity. History of difficulty donating blood or donating more than 500 ml of blood in less than seven days before the start of the study.

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 the BEAR statistical software (Release V2.7.7). Each volunteer will be randomly assigned to one of the 2 different sequence of treatments according to the order of entering the study which will be allocated after screening.

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
2021-09-21, 1400/06/30

Ethics committee reference number
1399.203.IR.SBMU.PHARMACY.REC.

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic Karen Pharma and Food Supplement Co. Valsartan 160 mg tablet with brand Diovan® 160 mg tablet Novartis pharmaceuticals..

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)

Timepoint
During 2 months 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
During 2 months 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 group: (test): Valsartan 160 mg Tablet, produced by Karen Pharma and Food Supplement Co. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
Category
Treatment - Drugs

2

Description
Intervention group: (reference):Diovan® 160 mg Tablet, produced by Novartis pharmaceuticals is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product.
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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Postal code
4635314588
Phone
+98 21 9253 5647
Email
mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karen Pharma and Food Supplement Co.
Full name of responsible person
Ali Mazidi
Street address
No: 3, Western Nahid st. Africa Blvd.
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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?
No
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
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Person responsible for scientific inquiries

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Position
Principal investigator

Latest degree
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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