

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

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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 (C_{max})

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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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

Pharmacy

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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

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Person responsible for updating data

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Latest degree

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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