

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of Rosuvastatin 40 mg tablets of Karen Pharma and Food Supplement Co. and Apotex Inc. in 24 healthy male under fasting.

Protocol summary

Study aim

This study was performed to compare the pharmacokinetics and endotracheal parameters of the formulation of 40 mg rosuvastatin calcium tablet of Karen Company as a test product with the formulation of 40 mg Rosuvastatin calcium tablet of Apotex Inc. As a reference product and evaluation of biological equivalence of these two formulations is done.

Design

Randomized, single-dose, crossover comparative bioequivalence study of Rosuvastatin 40 mg of Karen Pharma and Food Supplement Co. and Apotex Inc. 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 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. Known hypersensitivity or idiosyncratic reaction to Rosuvastatin or inactive ingredients. History or existence of hepatic or GI diseases or any other condition that could interfere with the absorption, distribution, excretion or metabolism of the drug.

Intervention groups

Intervention group (test): Rosuvastatin 40 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): Apo-Rosuvastatin 40 mg tablet, produced by Apotex Inc. 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: **IRCT20180620040164N25**

Registration date: **2022-04-29, 1401/02/09**

Registration timing: **retrospective**

Last update: **2022-04-29, 1401/02/09**

Update count: **0**

Registration date

2022-04-29, 1401/02/09

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

2021-12-24, 1400/10/03

Expected recruitment end date

2022-01-10, 1400/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of Rosuvastatin 40 mg tablets of Karen Pharma and Food Supplement Co. and Apotex Inc. in 24 healthy male under fasting.

Public title

Bioequivalence study of Rosuvastatin 40 mg tablet 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 or idiosyncratic reaction to Rosuvastatin or inactive ingredients. History or existence of hepatic or GI diseases or any other condition that could interfere with the absorption, distribution, excretion or metabolism of the drug. Current or chronic history of liver disease, or know hepatic or biliary abnormalities. 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 alcohol, 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.

AgeFrom **18 years** old to **45 years** old**Gender**

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample sizeTarget sample size: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

The randomization schedule will be generated with <https://www.sealedenvelope.com/simple-randomiser/v1/lits>. 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

2020-08-23, 1399/06/02

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.182

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

Bioequivalence investigation of the generic Karen Pharma and Food Supplement Co. Rosuvastatin 40 mg Tablet with brand Apo-Rosuvastatin Apotex Inc. Tablet.

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):Rosuvastatin 40 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):Apo-Rosuvastatin 40 mg Tablet, produced by Apotex INC. is the reference 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

Tehran

Province

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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.

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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Sharif innovation station, North Habibollah, Hosseini Squ., Teymouri St., Tarasht

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Email

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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طرشت، خیابان تیموری، میدان حسینی، خیابان حبیب الله شمال،
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Person responsible for updating data

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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