Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative bioequivalence study of Rosuvastatin 40 mg tablets of Dorsa Pharmaceutical Co. and Asterazeneca 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 Dorsa Pharmaceutical Co. as a test product with the formulation of 40 mg Rosuvastatin calcium tablet of Asterazeneca 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 Dorsa Pharmaceutical Co. and Asterazeneca in 24 healthy male under fasting.

Settings and conduct
The clinical phase is open-labelled and 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.

Intervention groups
Intervention group (test): Rosuvastatin40 mg Tablet, produced by Dorsa Pharmaceutical 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): Crestor 40 mg tablet, produced by Asterazeneca 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: **IRCT20180620040164N22**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **prospective**

Last update: **2022-02-26, 1400/12/07**
Update count: **0**

Registration date
2022-02-26, 1400/12/07

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
2022-03-02, 1400/12/11

Expected recruitment end date
2022-03-09, 1400/12/18

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 Dorsa Pharmaceutical Co. and Asterazeneca 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.

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
2021-08-31, 1400/06/09

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.127

Health conditions studied

1

Description of health condition studied
Bioequivalence investigation of the generic Dorsa Pharmaceutical Co. Rosuvastatin40 mg Tablet with brand Crestor Asterazeneca Tablet.

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):Rosuvastatin 40 mg Tablet, produced by Dorsa Pharmaceutical 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: (refrence): Crestor 40 mg Tablet, produced by Asterazeneca is the refrence 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
Tehran
Postal code
4635314588
Phone
+98 21 9253 5647
Email
mina.hasanabadi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dorsa Pharmaceutical Co.
Full name of responsible person
Amir esmael Saghafinia
Street address
Teimori-Shahid Salehi Blv-Fanavari Tarash Tower-8th floor
City
Tehran
Province
Tehran
Postal code
1459965204
Phone
+98 21 5461 2000
Email
info@dorsadarou.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dorsa Pharmaceutical 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