Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Rosuvastatin 40mg tablet of Cosar Pharm Co., IRAN and Crestor 40mg tablet of Astra-Zeneca in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim
A randomized, crossover bioequivalence study of single dose of test formulation (one tablet of Rosuvastatin 40mg produced by Cosar Pharm. Co.) in comparison of reference product (one tablet of Crestor 40mg) by means of AUC0-t and Cmax in healthy, adult human subjects under fasting conditions.

Design
A randomized, open label, single dose, crossover, bioequivalence study in 24 healthy subjects under fasting condition

Settings and conduct
This study is carried out in Core Research Center of Zahedan University of Medical Sciences located in Imam Ali Hospital in Zahedan. There is a separate space for sampling and forecasting emergency situations in order to accommodate and rest the volunteers. This crossover and open label study was performed on 24 healthy volunteers. The volunteers' health is verified by the project physician prior to entry into the study, and the volunteers' status is regularly monitored by the project physician on the day of drug administration. This study will be covered by insurance in order to compensate for any adverse effects.

Participants/Inclusion and exclusion criteria
Main Inclusion criteria: Healthy subjects aged between 18 -50 years old and weighted between 50 – 100 kg\\ Main exclusion criteria: Clinically relevant deviations from normal; Donation a unit of blood or participated in another clinical trial within the last two months; History of drug or alcohol abuse; Used any medication within 7-14 days before the first treatment; History of allergic to statins

Intervention groups
Intervention: Single dose of one Rosuvastatin 40mg tablet of Cosar Pharm Co., IRAN Control: Single dose of one Crestor 40mg tables of AstraZeneca

Main outcome variables
Plasma concentration of Rosuvastatin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190706044111N19**
Registration date: **2020-09-27, 1399/07/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-27, 1399/07/06**
Update count: **0**

Registration date
2020-09-27, 1399/07/06

Registrant information

Name
Ladan Tayebi

Name of organization / entity
Pars Biopharmacy Research Co.

Country
Iran (Islamic Republic of)

Phone
+98 21 8895 6061

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l.tayebi@parsbiopharmacy.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Rosuvastatin 40mg tablet of Cosar Pharm Co., IRAN and Crestor 40mg tablet of Astra-Zeneca in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Rosuvastatin 40mg tablet of Cosar Pharm Co., IRAN

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
- Aged between 18 - 50 years - Body weight between 50 – 100 kg - Having good health on the basis of medical history and physical & clinical examination - Understand the procedures and give written informed consent

Exclusion criteria:
Subject had undergone surgery of the gastro-intestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last two months before the first treatment. Subject had a history of drug or alcohol abuse. Subject who smokes more than 10 cigarettes per day. Subject had used any prescription medication within 14 days, or any non-prescription medication within 7 days, before the first treatment.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each volunteer, 2 times take medicine in the study. One-time test product and the other time reference product with at least one week wash-out period.

Randomization (investigator's opinion)
Randomized

Randomization description
Using Excel software, each subject will be randomly assigned to one of the two sequence AB or BA in a balanced manner. Due to the cross-over study, 24 participants were assigned to test and reference products as well as reference-test products using the Excel command rand command.

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 Zahedan University of medical Sciences

Street address
Dr. Hessabi square Zahedan University of Medical Sciences

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2020-08-23, 1399/06/02

Ethics committee reference number
IR.ZAUMS.REC.1399.198

Health conditions studied

1

Description of health condition studied
Hyperlipidemia

ICD-10 code
E78.5

ICD-10 code description
Hyperlipidemia, unspecified

Primary outcomes

1

Description
Plasma concentration of Rosuvastatin

Timepoint
at 0 (before dosing), 1.0, 2.0, 3.0, 4.0, 4.5, 5.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. after dosing

Method of measurement
High Performance Liquid Chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Single dose of one Rosuvastatin 40mg tablet of Cosar Pharm Co., IRAN
Category
N/A

2

Description
Control group: Single dose of one Crestor 40mg tablet of AstraZeneca
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Core Research Lab. of ZAUMS
Full name of responsible person
Gholamreza Komeili
Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway
City
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Province
Sistan-va-Balouchestan
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9816743111
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+98 54 3329 5664
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+98 54 3329 5665
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crl@zaums.ac.ir
Web page address
http://crl.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cosar Pharm. Co.
Full name of responsible person
Ali Ghaemi Tehrani
Street address
Darougar Street, 17Km old way Karaj-tehran
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Province
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Postal code
1388154311
Phone
+98 21 4492 1575
Fax
+98 21 4492 1077
Email
info@cosarpharm.com
Web page address
http://cosarpharm.com/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cosar Pharm. 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
Pars Biopharmacy Research Co.
Full name of responsible person
Ladan Tayebi
Position
Managing Director
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available