

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 AUC_{0-t} and C_{max} 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

Email address

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

Zahedan

Province

Sistan-va-Balouchestan

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Email

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

City

Tehran

Province

Tehran

Postal code

1388154311

Phone

+98 21 4492 1575

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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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Full name of responsible person

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Position

Managing Director
Latest degree
Medical doctor
Other areas of specialty/work
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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