Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Rosuvastatin 20mg of Sobhan Darou Pharm Co., IRAN and Crestor 20 mg in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

To characterize the rate and extent of bioavailability of test in comparison of reference product after single dose administration in healthy subjects under fasting condition. - To assess the bioequivalence of test formulation (Rosuvastatin 20mg tablet of Sobhan Darou Pharm Co.) with reference product (Crestor 20mg tablet) by means of AUC0-t and Cmax (using pharmacokinetic & statistical software). - Safety and tolerability evaluation of test product in comparison with reference in subjects (Recording signs of side effects in each period of the study).

Design

A randomized, open label, two treatments, two periods, single dose, crossover, bioequivalence study of Rosuvastatin 20mg tablet of Sobhan Darou Pharm Co., IRAN in comparison of Crestor 20mg tablet of Astra-Zeneca in 24 healthy subjects under fasting condition

Settings and conduct

1- 24 healthy subjects enroll in this project. Volunteers provide written informed consent. 2- A single dose of 2*20 mg rosuvastatin will administer, in each study period. 3-The Blood samples collect before and at 1.0, 2.0, 3.0, 4.0, 4.5, 5.0, 6.0, 8.0, 10.0, 24.0 & 48.0 hr. post-dose. 4- The treatment phases (test & reference products) separate by a washout period of at least 7 days.

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 three 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 2 tablets of Rosuvastatin 20mg of Sobhan Darou Pharm Co. Control: Single dose of 2 tablets of Crestor 20mg of Astra-Zeneca

Main outcome variables

Plasma concentration of rosuvastatin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N15**
Registration date: **2020-02-23, 1398/12/04**
Registration timing: **retrospective**

Last update: **2020-02-23, 1398/12/04**
Update count: **0**

Registration date

2020-02-23, 1398/12/04

Registrant information

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Ladan Tayebi
Name of organization / entity
Pars Biopharmacy Research Co.
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01
Expected recruitment end date
2020-02-20, 1398/12/01
Actual recruitment start date
2019-11-14, 1398/08/23
Actual recruitment end date
2019-11-29, 1398/09/08
Trial completion date
2019-11-29, 1398/09/08

Scientific title
A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Rosuvastatin 20mg of Sobhan Darou Pharm Co., IRAN and Crestor 20 mg in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Rosuvastatin 20mg of Sobhan Darou Pharm Co.
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 showed clinically relevant deviations from normal in physical examination (BMI less than 18 or mor than 25, ...) 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 three 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. Subject had a history of allergic to statins
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.
Actual sample size reached: **24**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Each volunteer, 2 times took 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.
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
Ethicc committee of Shahid Beheshti University of Medical Sciences
Street address
Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2017-02-21, 1395/12/03
Ethics committee reference number
IR.SBMU.REC.1395.48

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, 7.0, 8.0, 10.0, 24.0 & 48.0 hr. post-dose
Method of measurement
High Performance Liquid Chromatography (HPLC)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Single dose of 2 tablets of Rosuvastatin 20mg of Sobhan Darou Pharm Co., IRAN
Category
Other

2

Description
Control group: Single dose of 2 tablets of Crestor 20mg tablet of Astra-Zeneca
Category
Other

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
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crl@zaums.ac.ir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sobhan Darou Pharm. Co.
Full name of responsible person
Ali sharif Alam
Street address
No. 295, West Dr. Fatemi St.
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Postal code
۱۴۱۱۸۵۳۶۹۵
Phone
+98 21 6656 8181
Fax
+98 21 6694 8553
Email
info@sobhandarou.com
Web page address
http://www.sobhandarou.com/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sobhan Darou 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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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