

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 AUC_{0-t} and C_{max} (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

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

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 more 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

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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

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

Sobhan Darou Pharm. Co.

Full name of responsible person

Ali sharif Alam

Street address

No. 295, West Dr. Fatemi St.

City

Tehran

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۱۴۱۱۸۵۳۶۹۵

Phone

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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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inquiries

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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

Person responsible for updating data

Contact

Name of organization / entity

Pars Biopharmacy Research Co.

Full name of responsible person

Ladan Tayebi

Position

Managing Director

Latest degree

Medical doctor