Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Rosuvastatin 20 mg tablet of Aburaihan Pharm Co., IRAN and Crestor 20 mg tablet of Astra-Zeneca 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 (Atorvastatin 20mg tablet of Aburaihan Pharm Co., IRAN) with reference product (Crestor 20mg tablet of Astra-Zeneca) by means of AUC0-t and Cmax . - Safety and tolerability evaluation of test product in comparison with reference in subjects

Design

A randomized, open label, two treatments, two periods, single dose, crossover, bioequivalence study of Rosuvastatin 20 mg tablet of Aburaihan Pharm Co., IRAN in comparison of Crestor 20 mg 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 separate by a washout period of at least 7 days. 5- Plasma samples will transfer to analytical Lab. to measure rosuvastatin in the plasma by means of HPLC.

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 Rosuvastatin 20mg tablet of Aburaihan Pharm Co., IRAN Control: single dose of Crestor 20mg tablet of Astra-Zeneca

Main outcome variables

Plasma concentration of rosuvastatin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N9**
Registration date: **2019-09-13, 1398/06/22**
Registration timing: **retrospective**

Last update: **2019-09-13, 1398/06/22**
Update count: **0**

Registration date

2019-09-13, 1398/06/22

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

2018-10-23, 1397/08/01

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

2019-01-10, 1397/10/20

Actual recruitment end date

2019-03-08, 1397/12/17

Trial completion date

2019-03-08, 1397/12/17

Scientific title

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

Public title

Bioequivalence study of Rosuvastatin 20 mg tablet of Aburaihan 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 showed clinically relevant deviations from normal in physical examination. 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 took 2 times 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)

Not randomized

Randomization description

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

2018-09-02, 1397/06/11

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.358

Health conditions studied

1

Description of health condition studied

Hyperlipidemia

ICD-10 code

ICD-10 code description

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. after dosing

Method of measurement

HPLC

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Single dose of Rosuvastatin 20mg tablet of Aburaihan Pharm Co., IRAN
Category
Other

2

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Core Research Lab. of Zahedan University of Medical SciencesS
Full name of responsible person
Gholamreza Komeili
Street address
Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway
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+98 54 3329 5664
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crl@zaums.ac.ir
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Aburaihan Pharm Co.
Full name of responsible person
Seifi Payam
Street address
Tirandaz Ave. No.1, Tehran 16
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Tehran
Postal code
1654613111
Phone
+98 21 7770 7173
Fax
+98 21 7770 2066
Email
info@aburaihan.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Aburaihan 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.
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Ladan Tayebi
Position
Managing Director
Latest degree
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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