Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

A randomized, open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Aristatin 10mg tablet of Arya Pharm Co., IRAN and Crestor 10mg 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 (Aristatin 10mg tablet of Arya Pharm Co., IRAN) with reference product (Crestor 10mg 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 Aristatin 10mg tablet of Arya Pharm Co., IRAN in comparison of Crestor 10mg 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*10 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 Aristatin 10mg tablet of Arya Pharm Co., IRAN Control: single dose of Crestor 10mg tablet of Astra-Zeneca

Main outcome variables

Plasma concentration of rosuvastatin

General information

Reason for update

This Study was cancelled by sponsor (Arya Pharm. Co.)

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N8**
Registration date: **2019-09-09, 1398/06/18**
Registration timing: **prospective**

Last update: **2022-01-10, 1400/10/20**
Update count: **1**

Registration date

2019-09-09, 1398/06/18

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
2019-10-23, 1398/08/01
Expected recruitment end date
2020-05-20, 1399/02/31
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 Aristatin 10mg tablet of Arya Pharm Co., IRAN and Crestor 10mg tablet of Astra-Zeneca in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Aristatin 10mg tablet of Arya 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.
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
Ethics 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
2018-11-04, 1397/08/13
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.624

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: Intervention group: Single dose of

Aristatin 10mg tablet of Arya Pharm Co., IRAN

Category

Other

2

Description

Control group: Single dose of Crestor 10mg tablet of Astra-Zeneca

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Core Research Lab. of Zahedan University of Medical Sciences

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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9816743111

Phone

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Fax

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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

Arya Pharm Company

Full name of responsible person

Shabestari Rahim

Street address

Karaj Makhsous Highway, daroupakhsh Ave.

City

Tehran

Province

Tehran

Postal code

۱۳۹۷۱۳۳۱۱۱

Phone

+98 21 4498 1081

Fax

+98 21 4498 9243

Email

info@aryapharm.com

Web page address

http://aryapharm.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arya Pharm Company

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 scientific inquiries

Contact

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Web page address

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