Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

An open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Aristatin 5 mg tablet of Arya Pharm Co., IRAN and Crestor 5 mg tablet of Astra-Zeneca in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

Crestor 5 mg tablet of Astra-Zeneca can be changed by Aristatin 5 mg tablet of Arya Pharm Co., IRAN?

Design

An open label, two treatments, two periods, single dose, crossover, bioequivalence study of Aristatin 5 mg tablet of Arya Pharm Co., IRAN in comparison of Crestor 5 mg tablet of Astra-Zeneca in 24 healthy subjects under fasting condition

Settings and conduct

Sampling center: Core Research Lab. of Zahedan University of Medical Sciences Method of sampling: 1- Subject no. and condition: 24 healthy subjects 2- Dose & administration: A single dose of 2*5 mg rosuvastatin under fasting condition 3-Sampling time: 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- Period of treatment phases: two times separate by a washout period of at least 7 days. 5- Method analysis of rosuvastatin in the plasma: 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 5 mg tablet of Arya Pharm Co., IRAN Control: single dose of Crestor 5 mg 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: **IRCT20190706044111N12**
Registration date: **2019-11-10, 1398/08/19**
Registration timing: **prospective**

Last update: **2021-06-03, 1400/03/13**
Update count: **1**

Registration date

2019-11-10, 1398/08/19

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

2019-11-22, 1398/09/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An open label, two treatments, two periods, two sequence, single dose, crossover, bioequivalence study of Aristatin 5 mg tablet of Arya Pharm Co., IRAN and Crestor 5 mg tablet of Astra-Zeneca in 24 healthy adult subjects under fasting condition

Public title

Bioequivalence study of Aristatin 5 mg tablet of Arya Pharm

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

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.1397.359

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 Aristatin 5 mg tablet of Arya Pharm Co., IRAN

Category

Other

2

Description
Control group: Single dose of Crestor 5 mg 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
City
Zahedan
Province
Sistan-va-Balouchestan
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9816743111
Phone
+98 54 3329 5664
Fax
+98 54 3329 5665
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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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