Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim

- Bioequivalence study of single dose of test formulation (Rosuvastatin 20mg tablet) in comparison of reference product (Crestor 20mg tablet) by means of AUC0-t and Cmax in healthy, adult human subjects under fasting conditions.

Design

A randomized, open label, two treatments, two periods, single dose, crossover, bioequivalence study of Rosuvastatin 20mg tablet of Tolidarou 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 tablets of rosuvastatin 20 mg 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. after dosing. 4- The treatment phases separate by a washout period of at least 7 days. 5- Drug Prescription and sampling take place in Core Research Lab. of Zahedan University of Medical Sciences.

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 (BMI less than 18 and more than 25); 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 Tolidarou Pharm Co., IRAN 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: **IRCT20190706044111N16**
Registration date: **2020-03-07, 1398/12/17**
Registration timing: **retrospective**

Last update: **2020-03-07, 1398/12/17**
Update count: **0**

Registration date

2020-03-07, 1398/12/17

Registrant information

Name
Ladan Tayebi
Name of organization / entity
Pars Biopharmacy Research Co.
Country
Iran (Islamic Republic of)
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+98 21 8895 6061
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

1978-04-21, 1357/02/01

Expected recruitment end date

1979-03-20, 1357/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Bioequivalence study of Rosuvastatin 20mg tablet of Tolidarou 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 with BMI less than 18 or more than 30 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 two 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)

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.1395.50

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. after drug administration

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 tablet of Tolidarou 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
Web page address
http://crl.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tolidaru Pharmaceutical Company
Full name of responsible person
Dabir-Syaghi Alireza
Street address
ST Yadegar , Saveh highway
City
Tehran
Province
Tehran
Postal code
1371616314
Phone
+98 21 6117
Fax
+98 21 6662 0175
Email
info@toliddaru.ir
Web page address
http://www.toliddaru.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tolidaru Pharmaceutical 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
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Other areas of specialty/work
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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