

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 AUC_{0-t} and C_{max} 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)

Phone

+98 21 8895 6061

Email address

l.tayebi@parsbiopharmacy.com

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

City

Zahedan

Province

Sistan-va-Balouchestan

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9816743111

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+98 54 3329 5664

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+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**

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

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Pars Biopharmacy Research Co.

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Tehran

Province**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