Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

In-vivo Bioequivalence Test of Rosuvastatin tablets in comparison with brand name drug (CRESTOR® 20mg F.C Tab.) Made by ASTRA-Zeneca, UK.

Protocol summary

Study aim

In- Vivo Bioequivalence study of Rosuvastatin tablet 20mg Hakim with brand drugs (CRESTOR® 20mg, ASTRA-ZENECA, Belgium) in Iranian healthy volunteers.

Design

Single dose, randomized, two sequences, two period crossover with a washout period.

Settings and conduct

This study will be conducted in two-way, cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of twenty-four hours.The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form.In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

Participants/Inclusion and exclusion criteria

24 participants will be selected from non-smoking, not pregnant people with no history of heart, kidney and liver disease or dis functions with both sex (male&female). The ages and BMIs of participant should be in the range of 18-60 and 18-25 respectively.

Intervention groups

Both groups received in cross-over design medication and testing at two different cross-sections and Therefor,the test results are independent of individual differences and it will only show the difference in the formulation of the two drugs.

Main outcome variables

Maximum plasma concentration of the drug, time to reach the maximum plasma concentration, drug excretion half-life, drug excretion constant

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046010N11**
Registration date: **2020-10-24, 1399/08/03**
Registration timing: **prospective**

Last update: **2020-10-24, 1399/08/03**
Update count: **0**

Registration date

2020-10-24, 1399/08/03

Registrant information

Name

Javad Shokri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3661 4125

Email address

shokri.j@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-03, 1399/10/14

Expected recruitment end date

2021-07-05, 1400/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In-vivo Bioequivalence Test of Rosuvastatin tablets in comparison with brand name drug (CRESTOR® 20mg F.C Tab.) Made by ASTRA-Zeneca, UK.

Public title

In-vivo Bioequivalence Test of Rosuvastatin tablets with brand name drug CRESTOR® 20mg F.C Tab. Made by ASTRA-Zeneca, UK in Iranian healthy volunteers.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health Body mass index(18-28) Informed consent Age(18-60)

Exclusion criteria:

Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Candidates are not aware of the test drug or brand name. In a one-blind study, information that could distort the test result is hidden from the candidates, but the person in charge of the test is aware of it. Rosuvastatin and Rosuvastatin ® are removed from their packaging by the executor and placed in similar and coded cans. Volunteers will not be informed about receiving the brand or test dosage form.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

No.48,Ferdows street, Ferdowsi Sq.

City

Tabriz

Province

East Azarbaijan

Postal code

5167874434

Approval date

2020-09-27, 1399/07/06

Ethics committee reference number

IR.TBZMED.REC.1399.666

Health conditions studied

1

Description of health condition studied

In this study, the disease is not examined. Subject bioequivalence test and reference tablets Razvvastatyn studied.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination of blood drug concentration.

Timepoint

Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours.

Method of measurement

High Performance Liquid Chromatography with tandem mass spectroscopy detector

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Single dose Rosuvastatin tablet 20mg Hakim Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Simin Baspar Teyf Gostar Company
Full name of responsible person
Javad Shokri
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mehrdad alimiyan
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1913774951
Phone
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Email
info@hakimpharm.com

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz University of Medical Sciences

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Javad Shokri
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Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
These date are as secure between researcher and related industries.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only protocol and methods of study are sharable.
When the data will become available and for how long
After finishing of the protocol (Probably 6 months receiving IRCT code)
To whom data/document is available
Pharmaceutical and medical sciences researchers.
Under which criteria data/document could be used
Projects information's for any publications is not allowed.
From where data/document is obtainable
Contact with E-mail of the main researcher.
What processes are involved for a request to access data/document
Personal and academic details and the aim of the request.
Comments