

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparative bioequivalence study of the Atorvastatin 80-mg/Ezetimibe 10-mg Tablet manufactured by Nikasa Pharmed Pharmaceutical Company

Protocol summary

Study aim

Demonstration of bioequivalence of Atorvastatin 80-mg/Ezetimibe 10-mg tablet of Nikasa Pharmed Pharmaceutical Company with Liptruzet® tablet manufactured by Merck after single dose administration.

Design

Single dose, randomized and crossover bioequivalence study of Atorvastatin 80-mg/Ezetimibe 10-mg tablet of Nikasa Pharmed Pharmaceutical Company with Liptruzet® tablet (Merck) in 24 healthy male volunteers under fasting condition.

Settings and conduct

24 healthy male volunteers will receive each of test or reference Atorvastatin 80-mg/Ezetimibe 10-mg tablet in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days, If the first sequence receives Iranian medicine, they will receive brand medicine. Blood samples will be taken from all participants before and after receiving the drug at 0 (Before dosing), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 12, 24, 48, 72 and 96 hours after dosing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy male volunteers in the age range of 18-60 years; BMI 18-30. Exclusion Criteria: history of allergy or idiosyncrasy to atorvastatin and ezetimibe or any of the inactive components of the formulation. Candidates with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg. Smokers who smoke more than 10 cigarettes a day. Take any medication within 2 weeks before receiving the medication.

Intervention groups

Atorvastatin 80-mg/Ezetimibe 10-mg tablet of Nikasa Pharmed Pharmaceutical Company is the test product. Intervention group 2: Liptruzet® tablet manufactured by Merck is the reference product. In each period, 12 of 24 subjects will be given single dose of this product. After the washout period, the volunteers are placed in the

opposite group.

Main outcome variables

Peak Plasma Concentration (C_{max}); Area under the concentration-time curve (AUC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200407046981N34**

Registration date: **2022-06-29, 1401/04/08**

Registration timing: **prospective**

Last update: **2022-06-29, 1401/04/08**

Update count: **0**

Registration date

2022-06-29, 1401/04/08

Registrant information

Name

Fatima Molavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 2700

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-09, 1401/09/18

Expected recruitment end date

2023-02-07, 1401/11/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of the Atorvastatin 80-mg/Ezetimibe 10-mg Tablet manufactured by Nikasa Pharmed Pharmaceutical Company

Public title

Study of absorption and elimination rate of Atorvastatin 80-mg/Ezetimibe 10-mg tablet (Lipzib®) in comparison with Atorvastatin 80-mg/Ezetimibe 10-mg brand tablet (Liptruzit®)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The weight limit of each volunteer should be between 60 and 100 kg.. All volunteers must be non-smokers.They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed Candidates who have consented to the consent form.

Exclusion criteria:

Known hypersensitivity or idiosyncratic reaction to Atorvastatin and Ezetimibe or any ingredients. Subjects with BP ≤ 90/60 mm/Hg or BP ≥ 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily. Taking any medicine during two weeks before dosing.

Age

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

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 and group B will receive intervention 2, and after the first period, the interventions of the both groups will change for the second period.

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 Tabriz University of Medical Science

Street address

Third floor, central building No. 2, Golgasht street, Tabriz University of Medical Science,

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.TBZMED.REC.1401.236

Health conditions studied**1****Description of health condition studied**

Bioequivalence study

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Peak Plasma Concentration (Cmax)

Timepoint

At 0 (Before dosing), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 12, 24, 48, 72 and 96 hours

Method of measurement

High-performance liquid chromatography—mass spectrometry (HPLC-MS-MS)

Secondary outcomes**1****Description**

AUC (Area Under the Concentration-Time Curve)

Timepoint

At 0 (Before dosing), 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 6, 8, 12, 24, 48, 72 and 96 hours

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA) or SPSS

Intervention groups

1

Description

Intervention group 1: In this group, volunteers are given a single oral dose of Atorvastatin 80-mg/Ezetimibe 10-mg tablet produced by Nikasa Pharmed Co. (Domestic). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, volunteers are given a single oral dose of Atorvastatin 80-mg/Ezetimibe 10-mg tablet (Liptruzet ®), produced by Merck Company (Brand). In each period, 12 of 24 subjects will be given single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center

Full name of responsible person

Hamed Hamishehkar

Street address

Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshgah Blvd, Tabriz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nikasa Pharmed Pharmaceutical Company

Full name of responsible person

Pardis Kalantarian

Street address

Jinnah Highway - Shahid Golab Boulevard - No. 53 - Unit 13

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nikasa Pharmed 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

Tabriz University of Medical Sciences

Full name of responsible person

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Full name of responsible person

Fatima Molavi

Position

Non-Faculty Academic Position

Latest degree

Medical doctor

Other areas of specialty/work

Pharmaceutics

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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

There is no further information

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available