Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Randomized, single-dose, crossover comparative bioequivalence study of the Atorvastatin 40 mg tablets produced by Daana pharmaceutical Co versus Lipitor® (Pfizer company) in 24 healthy males under fasting conditions

Protocol summary

Study aim
To demonstrate bioequivalence of single dose test formulation of Daana Atorvastatin 40 mg tablets versus Lipitor®(Pfizer Co.)

Design
Single dose, randomized and crossover bioequivalence study of Atorvastatin 40 mg tablets by Daana Co. with Lipitor® (Pfizer Co.) in 24 healthy male in two groups under fasting condition.

Settings and conduct
Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. Place for Blood and plasma sample analysis: Imam Reza Medical Research and Trainning Hospital. 24 healthy male volunteers will receive each of two test or reference Atorvastatin 40 mg tablets in random sequence according to the randomization schedule. The interval between receiving the medicine (washout period) is 7 days. Blood samples of volunteers at 0 (before dosing), 0.5، 1، 1.5، 2، 2.5، 3، 3.5، 4، 6، 8، 10، 12، 24 and 48 hour after dosing will be collected.

Participants/Inclusion and exclusion criteria
The weight limit for each volunteer is between 60 and 100 kg. They must be healthy in terms of liver, kidney, respiratory system, mental and other general health characteristics that will be assessed. Exclusion criteria: Known hypersensitivity or idiosyncratic reaction to Atorvastatin 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.

Intervention groups
Intervention group 1: In this group, volunteers are given a single oral dose of Atorvastatin 40 mg tablet of Daana Pharmaceutical Co.. Intervention group 2: In this group, volunteers are given a single oral dose of Lipitor® tablets of Pfizer company. After the washout period, the volunteers are placed in the opposite group. In fact, every single volunteers is used as control for himself.

Main outcome variables
Peak Plasma Concentration (Cmax); Area under the concentration-time curve (AUC).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200407046981N16**
Registration date: **2021-09-14, 1400/06/23**
Registration timing: **prospective**

Last update: **2021-09-14, 1400/06/23**
Update count: **0**

Registration date
2021-09-14, 1400/06/23

Registrant information

Name
Fatima Molavi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-02, 1400/07/10

Expected recruitment end date
2021-12-01, 1400/09/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Randomized, single-dose, crossover comparative bioequivalence study of the Atorvastatin 40 mg tablets produced by Daana pharmaceutical Co versus Lipitor® (Pfizer company) in 24 healthy males under fasting conditions

Public title
Study of absorption and elimination rate of Atorvastatin 40 mg tablets in comparison with standard tablets of Atorvastatin (Lipitor®).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The weight limit for each volunteer is 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.
Exclusion criteria:
Known hypersensitivity or idiosyncratic reaction to Atorvastatin 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 week 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
First, a table of random numbers from 1 to 24 is created. The table numbers are assigned to individuals in the order in which the candidates enter the list on the day of the experiment, and the candidates in two groups with numbers 1-12 and numbers 13-24 will receive reference and test medicine, respectively.
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, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-08-02, 1400/05/11
Ethics committee reference number
IR.TBZMED.REC.1400.470

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, 10, 12, 24 and48 hour after dosing
Method of measurement
High-performance liquid chromatography—mass spectrometry (HPLC-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، 10، 12، 24 and 48 hour after dosing
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 40 mg tablet produced by Daana Co. (Domestic). After the washout period, the volunteers are placed in the Intervention group 2. In fact, every single volunteers is used as control for himself.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Atorvastatin 40 mg tablets (Lipitor), produced by Pfizer Company (Brand). After the washout period, the volunteers are placed in the Intervention group 1. In fact, every single volunteers is used as control for himself.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Drug Applied Research Center
Full name of responsible person
Dr Hamed Hamishehkar
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Drug Applied Research Center, In front of Shahid Madani Hospital, Daneshghah Blvd, Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Daana pharmaceutical company
Full name of responsible person
Ahmad Kharazi
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East Azerbaijan Province, Basmenj, Tehran - Tabriz Fwy
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East Azarbaijan
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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
Daana 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
Dr 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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Person responsible for updating data

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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
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
No - There is not a plan to make this available