

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Comparative bioequivalence study of single oral dose of Sitagliptin 50 mg tablet produced by Daana pharmaceutical Co versus Xelevia® (Merck company) in 24 healthy males under fasting conditions

Protocol summary

Study aim

To demonstrate bioequivalence of single dose test formulation of Daana Sitagliptin 50 mg tablets versus Xelevia® (Merck Co.)

Design

Single dose, randomized and crossover bioequivalence study of Sitagliptin 50 mg tablets by Daana Co. with Xelevia® (Merck 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 Training Hospital. 24 healthy male volunteers will receive each of two test or reference Sitagliptin 50 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), 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24 and 48 hours 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 Sitagliptin or any ingredients. Subjects with BP \leq 90/60 mm/Hg or BP \geq 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 Sitagliptin 50 mg tablet of Daana. Intervention group 2: In this group, volunteers are given a single oral dose of Xelevia® tablets of Merck 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: **IRCT20200407046981N15**

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

2021-10-22, 1400/07/30

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of single oral dose of Sitagliptin 50 mg tablet produced by Daana pharmaceutical Co versus Xelevia® (Merck company) in 24 healthy males under fasting conditions

Public title
Study of absorption and elimination rate of sitagliptin 50 mg tablets in comparison with standard tablets of Sitagliptin (Xelevia®).

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion 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 Sitagliptin or any ingredients. Subjects with BP \leq 90/60 mm/Hg or BP \geq 140/90 mm/Hg. Regular smoker who smokes more than ten cigarettes daily.

Age
From **18 years** old to **55 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
Individuals will be recruited voluntarily through advertising. 24 volunteers are randomly assigned to two sequences by lottery method. A table of random numbers from 1 to 24 is created and the table numbers are assigned to individuals in the order of entry of the candidates on the day of the test. At the moment of starting the study, candidates will receive reference medicine or test in two groups with numbers 1-12 and 13-24.

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

2021-08-23, 1400/06/01

Ethics committee reference number

IR.TBZMED.REC.1400.484

Health conditions studied

1

Description of health condition studied

En In this study, the disease is not examined. The subject of the study is the bioequivalence study of the Sitagliptin 50 mg of test and reference in healthy volunteers.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Peak Plasma Concentration (Cmax)

Timepoint

At 0 (before dosing), 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 6, 8, 10, 12, 24 and 48 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), 1, 2, 2.5, 3, 3.5, 4, 4.5, 5, 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 Sitagliptin 50 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 Sitagliptin 50 mg tablets (Xelevia), produced by Daana 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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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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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

Hamed Hamishehkar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

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Position

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Fatima Molavi

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Latest degree

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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