Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A randomized, open label, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Sitagliptin 50mg tablet of Alborzdarou Pharm Co., IRAN and Januvia 50mg tablet of MSD in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

- To characterize the rate and extent of bioavailability of test product in comparison of reference product after single oral dose administration in healthy, adult subjects under fasting conditions. - To assess the bioequivalence of test formulation (Sitagliptin 50mg tablet of Alborzdarou Pharm Co.) with reference product (Januvia 50mg tablet of MSD) by means of AUC0-t and Cmax . - Monitor the safety of the subjects participating in the study and tolerability of the test product in comparison with reference considering adverse events

Design

A randomized, open label, two treatments, two periods, single dose, crossover, bioequivalence study of Sitagliptin 50mg tablet of Alborzdarou Pharm Co., IRAN and Januvia 50mg tablet of MSD in 24 healthy adult subjects under fasting condition

Settings and conduct

1- 24 healthy subjects enroll in this project. Volunteers provide written informed consent. They find to be healthy based on the history and physical examinations as well as clinical laboratory profiles. 2- A single dose of 2*50 mg sitagliptin will administer, in each study period. 3-The Blood samples collect by direct vein punctures before and at 0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 24.0 & 36 hr. post-dose. 4- The treatment phases separate by a washout period of at least 7 days. 5- Plasma samples will transfer to analytical Lab. to measuring sitagliptin in the plasma

Participants/Inclusion and exclusion criteria

- Aged between 20 - 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

Intervention groups

- Ṡingle oral dose of Sitagliptin 50mg * 2 tablets of Alborzdarou Pharm Co., IRAN - Single oral dose of Januvia 50mg * 2 tablets of MSD

Main outcome variables

Plasma concentration of sitagliptin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N4**
Registration date: **2019-08-25, 1398/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-25, 1398/06/03**
Update count: **0**

Registration date

2019-08-25, 1398/06/03

Registrant information

Name
Ladan Tayebi
Name of organization / entity
Pars Biopharmacy Research Co.
Country
Iran (Islamic Republic of)
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+98 21 8895 6061
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-20, 1398/03/30

Expected recruitment end date
2019-12-21, 1398/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, open label, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Sitagliptin 50mg tablet of Alborzdarou Pharm Co., IRAN and Januvia 50mg tablet of MSD in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of Sitagliptin 50mg tablet of Alborzdarou Pharm Co., IRAN
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
- Aged between 20 - 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 showed clinically relevant deviations from normal in physical examination. 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 tree 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 this class of drugs
Age
From **20 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)
Not randomized
Randomization description
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
2019-03-03, 1397/12/12
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.1314

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of sitagliptine
Timepoint
0 (before dosing), 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0, 24.0 & 36.0 hr. post dose
Method of measurement
HPLC

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Single oral dose of Sitagliptin 50mg * 2 tablets of Alborzdarou Pharm Co.
Category
Other

2

Description
Control group: Single oral dose of Januvia 50mg * 2 tablets of MSD
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
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Sistan-va-Balouchestan
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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
Alborzdarou Pharm. Co.
Full name of responsible person
Ali Mortazavi
Street address
8th Hekmat street, Alborz Industrial City, Ghazvin
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Ghazvin
Province
Qazvin
Postal code
3431957693
Phone
+98 28 3222 1001
Fax
+98 28 3222 1001
Email
info@alborzdarouco.com
Web page address
http://www.alborzdarouco.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborzdarou Pharm. Co.
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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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