# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 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)
**Phone**
+98 21 8895 6061
**Email address**
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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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**Province**
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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
**City**
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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## 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**
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