Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Bioequivalence study of VITALOPHAGE 500mg tablet of Vitabiotics Pharmed Co., IRAN in comparison of CARBOPHAGE XR 500mg tablet of Merck in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

Bioequivalence study of VITALOPHAGE 500mg tablet of Vitabiotics Pharmed Co., IRAN in comparison of CARBOPHAGE XR 500mg tablet of Merck in 24 healthy adult subjects under fasting condition

Design

A randomized, open label, single dose, crossover, bioequivalence study in 24 healthy subjects under fasting condition

Settings and conduct

This study is carried out in Core Research Center of Zahedan University of Medical Sciences located in Imam Ali Hospital in Zahedan. There is a separate space for sampling and forecasting emergency situations in order to accommodate and rest the volunteers. This crossover and open label study was performed on 24 healthy volunteers. The volunteers' health is verified by the project physician prior to entry into the study, and the volunteers' status is regularly monitored by the project physician on the day of drug administration. This study will be covered by insurance in order to compensate for any adverse effects.

Participants/Inclusion and exclusion criteria

Main Inclusion criteria: Healthy subjects aged between 18 -50 years old and weighted between 50 – 100 kg\\ Main exclusion criteria:History of surgery of the gastro-intestinal tract ; Donation a unit of blood or participated in another clinical trial within the last two months; History of drug or alcohol abuse; Used any medication within 7- 14 days before the first treatment;

Intervention groups

Intervention: VITALOPHAGE 500mg tablet of Vitabiotics Pharmed Co., (IRAN), administration as a single dose and crossover; Control: CARBOPHAGE XR 500mg, produced by Merck company, administration as a single dose and crossover

Main outcome variables

Plasma concentration of metformin in plasma at 0 (before dosing), 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 24.0 & 48.0 hr. after dosing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190706044111N31**
Registration date: **2023-06-24, 1402/04/03**
Registration timing: **prospective**

Last update: **2023-06-24, 1402/04/03**
Update count: **0**

Registration date

2023-06-24, 1402/04/03

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

l.tayebi@parsbiopharmacy.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of VITALOPHAGE 500mg tablet of Vitabiotics Pharmed Co., IRAN in comparison of CARBOPHAGE XR 500mg tablet of Merck in 24 healthy adult subjects under fasting condition

Public title

Bioequivalence study of VITALOPHAGE 500mg tablet of Vitabiotics Pharmed Co., IRAN

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 18 - 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 had undergone surgery of the gastro-intestinal tract Subject had donated a unit of blood or participated in another clinical trial, within the last two months before the first treatment. Ŝubject 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.

Age

From **18 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)

Randomized

Randomization description

Using Excel software, each subject will be randomly assigned to one of the two sequence AB or BA in a balanced manner.

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 Zahedan University of medical Sciences

Street address

2nd Floor, Central Headquarters Building, University of Medical Sciences Campus, Dr. Hasabi Square, Gulf of Fars Blvd.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2023-05-14, 1402/02/24

Ethics committee reference number

IR.ZAUMS.REC.1402.057

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

Z79. 84

ICD-10 code description

Long term (current) use of oral hypoglycemic drugs

Primary outcomes

1

Description

Plasma concentration of metformin

Timepoint

At 0 (before dosing), 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 24.0 & 48.0 hr. after dosing

Method of measurement

Using High Performance Liquid Chromatography wit UV detector (HPLC/UV)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: VITALOPHAGE 500mg tablet of Vitabiotics Pharmed Co., (IRAN), administration as a

single dose and crossover

Category

Other

2

Description

Control group: CARBOPHAGE XR 500mg, produced by Merck company, administration as a single dose and crossover

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Core Research Lab. of ZAUMS

Full name of responsible person

Ebrahim Kord

Street address

Emam Ali Hospital, Salamat Blv., Khalij-e-Fars Highway

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5664

Fax

+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

Vitabiotix Pharmed

Full name of responsible person

Seyed Mir-Ebrahim Mir-Dehghan

Street address

Unit 6, No. 2, Erfan alley, Ghaem Magham St., Beheshti Aven.

City

Tehran

Province

Tehran

Postal code

1586715633

Phone

+98 21 8810 9515

Fax

+98 21 8810 3626

Email

info@vitabiotics.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vitabiotix Pharmed

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

Other

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

Street address

1st floor, Saeidi Dd end, Felestin Ave.

City

Tehran

Province

Tehran

Postal code

1416673971

Phone

+98 21 8895 6061

Fax

+98 21 8896 9958

Email

l.tayebi@parsbiopharmacy.com

Person responsible for scientific 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

Street address
1st floor, Saeidi Dd end, Felestin Ave.

City
Tehran

Province
Tehran

Postal code
1416673971

Phone
+98 21 8895 6061

Fax
+98 21 8896 9958

Email
l.tayebi@parsbiopharmacy.com

Person responsible for updating data

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

Street address
1st floor, Saeidi Dd end, Felestin Ave.

City
Tehran

Province
Tehran

Postal code
1416673971

Phone
+98 21 8895 6061

Fax
+98 21 8896 9958

Email
l.tayebi@parsbiopharmacy.com

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