

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Bioequivalence study of VITALOPHAGE 1000mg tablet of Vitabiotics Pharmed Co., IRAN in comparison of CARBOPHAGE XR 1000mg tablet of Merck in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim

Bioequivalence study of VITALOPHAGE 1000mg tablet of Vitabiotics Pharmed Co., IRAN in comparison of CARBOPHAGE XR 1000mg 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: Clinically relevant deviations from normal; 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 1000mg tablet of Vitabiotics Pharmed Co., (IRAN), single dose. Control: CARBOPHAGE XR 1000mg, produced by Merck company, single dose.

Main outcome variables

Plasma concentration of metformin 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: **IRCT20190706044111N30**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

Registration date

2023-06-21, 1402/03/31

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

2023-06-22, 1402/04/01

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 1000mg tablet of Vitabiotics Pharmed Co., IRAN in comparison of CARBOPHAGE XR 1000mg tablet of Merck in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of VITALOPHAGE 1000mg 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. 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.

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

2023-04-27, 1402/02/07

Ethics committee reference number

IR.ZAUMS.REC.1402.083

Health conditions studied

1

Description of health condition studied

Diabet

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 1000mg tablet of Vitabiotics Pharmed Co., (IRAN), single dose.

Category

Other

2**Description**

Control group: CARBOPHAGE XR 1000mg, produced by Merck company, single dose.

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

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Zahedan

Province

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Email

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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.

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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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Pars Biopharmacy Research Co.

Full name of responsible person

Ladan Tayebi

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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