Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A randomized, open label, single dose, crossover, bioequivalence study of GLICLAVITE 60mg tablet of Vitabiotics Pharmed Co., IRAN in comparison of DIAMICRON MR 60mg tablet of Servier in 24 healthy adult subjects under fasting condition

Protocol summary

Study aim
A randomized, open label, single dose, crossover, bioequivalence study of GLICLAVITE 60mg tablet of Vitabiotics Pharmed Co., IRAN in comparison of DIAMICRON MR 60mg tablet of Servier 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 GI surgery; 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: GLICLAVITE 60mg tablet of Vitabiotics Pharmed Co., (IRAN), single dose, cross over. Control: DIAMICRON MR 60mg, produced by Servier company, single dose, cross over.

Main outcome variables
Plasma concentration of gliclazide 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 & 72.0 hr. after dosing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190706044111N33**
Registration date: **2023-07-01, 1402/04/10**
Registration timing: **prospective**

Last update: **2023-07-01, 1402/04/10**
Update count: **0**

Registration date
2023-07-01, 1402/04/10

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
2023-09-23, 1402/07/01

Expected recruitment end date
2024-09-21, 1403/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, open label, single dose, crossover, bioequivalence study of GLICLAVITE 60mg tablet of Vitabiotics Pharmed Co., IRAN in comparison of DIAMICRON MR 60mg tablet of Servier in 24 healthy adult subjects under fasting condition

Public title
Bioequivalence study of GLICLAVITE 60mg 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
2023-05-14, 1402/02/24
Ethics committee reference number
IR.ZAUMS.REC.1402.058

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 gliclazide
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 & 72.0 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: GLICLAVITE 60mg tablet of Vitabiotics Pharmed Co., (IRAN), single dose, cross over.
Category
Other

2

Description
Control group: DIAMICRON MR 60mg, produced by Servier company, single dose, cross over.
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