Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Nov 2026

Bioequivalence study of Gliclazide 60 mg Extended Release Tablet (Tehran Chemie) versus Diamicron MR (SERVIER) Tablet after single oral dosing in healthy volunteers

Protocol summary

Study aim

Bioequivalence study of Gliclazide 60 mg Extended Release Tablet (Tehran Chemie) versus Diamicron MR (SERVIER) Tablet after single oral dosing in healthy volunteers

Design

Bioequivalence study, with control group, double-blind, randomized, on 24 volunteers, from each volunteer 20 blood samples were taken. Sealed envelope is used for randomization.

Settings and conduct

The subject of this biopharmaceutical and pharmacokinetic study is the location of Blood collection center of Tam Pouya Company located in Tehran. The study was blinded to the study participants by removing the drugs from the original package and placing the test and reference drugs in the same package, and the participants were not aware of the type of drug they were taking.The crossover design is such that the Iranian drug will be prescribed to the first group in the first week and to the second group in the second week. Brand medicine, on the contrary, Iranian medicine will be prescribed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: general health (liver, heart and kidneys), body mass index (18-28), informed consent, age (50-18) Exclusion criteria: smoking, history of cardiovascular disease, history of liver disease and Renal, alcohol and drug addiction, history of allergy to Gliclazide

Intervention groups

Intervention group: Receives one tablet of test drug (Gliclazide 60 mg Tablet Tehran Chemie). Control group: Receives one reference medicine Tablet (Diamicron 60 mg SERVIER Pharmaceutical Company).

Main outcome variables

Determination of blood concentration profile parity of brand drug with generics

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220111053692N7**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **prospective**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name

Bardia Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-13, 1401/12/22

Expected recruitment end date

2023-03-18, 1401/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Bioequivalence study of Gliclazide 60 mg Extended Release Tablet (Tehran Chemie) versus Diamicron MR (SERVIER) Tablet after single oral dosing in healthy volunteers

Public title
Bioequivalence study of Gliclazide 60 mg Extended Release Tablet (Tehran Chemie) versus Diamicron MR (SERVIER) Tablet after single oral dosing in healthy volunteers

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
18 to 55 years old Weight in range of 10 % proper body weight All volunteers should be in a good health condition on the basis of medical history ,physical examination , routine blood test. Possessing negative test for hepatitis B surface antigen (HBs-Ag), Antihepatitis-C antibody (anti-HCV) and anti-HIV. just man

Exclusion criteria:
Volunteers with hypersensitivity to Gliclazide were excluded. Those with known history of drug abuse. alcohol consumer or cigarette smokers. Taking medications that have drug interactions with gliclazide until one month before studying. disinclination to take the test. Blood donation or blood loss of more than 200 ml in the past month.

Age
From **18 years** old to **55 years** old

Gender
Male

Phase
Bioequivalence

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomly allocate people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are placed in random order. After entering the study, each candidate will take an envelope, numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 (test product) and group B will receive intervention 2 (reference product) and after the first period, the interventions of the two groups will be moved for the second period.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a Double-blind (participant) clinical trial. Gliclazide and Diamicron tablets are removed from the package by the administrator and placed in similar and coded cans.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committees of The Institute of Pharmaceutical Sciences,Tehran University of Medical Sciences

Street address
Research Institute of Pharmaceutical Sciences, second floor of the old building, Faculty of Pharmacy, Enqelab Square, 16 Azar St.

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2023-02-20, 1401/12/01

Ethics committee reference number
IR.TUMS.TIPS.REC.1401.126

Health conditions studied

1

Description of health condition studied
Bioequivalence study of Gliclazide 60 mg Extended Release Tablet (Tehran Chemie) versus Diamicron MR (SERVIER) Tablet after single oral dosing in healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Drug concentration in plasma samples

Timepoint
In times 0 ، 0/5، 1، 2 ،3، 4، 5، 6، 6/5 ، 7، 7/5 ، 8 ، 8/5 ، 9 ، 9/5 ، 10 ، 11 ، 24 ، 32 ، 48 Hours after the start of the intervention

Method of measurement
chromatography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receives one tablet of test drug (Gliclazide 60 mg tablet pharmaceutical company Tehran Chemie). Blood samples were taken from the volunteers for 48 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector.
Category
Other

2

Description
Control group: Receives one reference medicine tablet (Diamicron 60 mg SERVIER Pharmaceutical Company). Blood samples were taken from the volunteers for 48 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tam Pouya Consulting & Research Company
Full name of responsible person
Bardia Jamali
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran Chemie Pharmaceutical Company
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
Tam Pouya Consulting & Research Company
Full name of responsible person
Bardia Jamali
Position
manager
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available