

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Bioequivalence study of Gliclazide 80 mg Tablet (Tehran Chemie) versus Diamicon (SERVIER) Tablet after single oral dosing in healthy volunteers

#### Protocol summary

##### Study aim

Bioequivalence study of Gliclazide 80 mg Tablet (Tehran Chemie) versus Diamicon (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 80 mg tablet pharmaceutical company Tehran Chemie). Control group: Receives one reference medicine tablet (Diamicon 80 mg tablet SERVIER pharmaceuticals).

##### Main outcome variables

Drug concentration in plasma samples

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220111053692N16**

Registration date: **2024-02-29, 1402/12/10**

Registration timing: **prospective**

Last update: **2024-02-29, 1402/12/10**

Update count: **0**

##### Registration date

2024-02-29, 1402/12/10

##### Registrant information

##### Name

Bardia Jamali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8897 4707

##### Email address

info@tampouya.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-03-05, 1402/12/15

##### Expected recruitment end date

2024-03-11, 1402/12/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Bioequivalence study of Gliclazide 80 mg Tablet (Tehran Chemie) versus Diamicon (SERVIER) Tablet after single oral dosing in healthy volunteers

#### Public title

Bioequivalence study of Gliclazide 80 mg mg

#### 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 the 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 Diamicon tablets are removed from the package by the administrator and placed in similar and coded cans. Medicine and placebo are the same in terms of the method of administration

#### 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

2024-01-17, 1402/10/27

#### Ethics committee reference number

IR.TUMS.TIPS.REC.1402.153

## Health conditions studied

### 1

#### Description of health condition studied

Bioequivalence study of Gliclazide 80 mg Tablet (Tehran Chemie) versus Diamicon (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 , 1, 2, 2/5 , 3, 3/5, 4, 4/5 , 5, 5/5 , 6, 6/5, 7, 7/5, 8, 9, 10, 18, 24, 30, 36 , 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 80 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 (Diamicon 80 mg tablet SERVIER pharmaceuticals). 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

**Street address**

No. 7 ,Navard Ave ,17 Shahrivar St., 5th Km Fat`h Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1378756411

**Phone**

+98 21 6107 4387

**Fax**

+98 21 6107 4070

**Email**

info@tampouya.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran Chemie Pharmaceutical Company

**Full name of responsible person**

Dr. Ali Mehramizi

**Street address**

Navard Ave, 17 Shahrivar St.,5th Km Fat`h Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1378756411

**Phone**

+98 21 6680 0225

**Fax**

+98 21 6107 4132

**Email**

info@tehranchemie.com

**Web page address**

https://www.tehranchemie.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**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**

Industry

**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**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Unit 1, No. 1, Crot Building, Jahan mehr Street, Shahid Gomnam Street, Fatemi Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1431653941

**Phone**

+98 21 8897 4707

**Fax**

+98 21 8897 4707

**Email**

info@tampouya.com

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

Tam Pouya Consulting & Research Company

**Full name of responsible person**

Bardia Jamali

**Position**

Manager

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Unit 1, No. 1, Crot Building, Jahan mehr Street, Shahid  
Gomnam Street, Fatemi Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1431653941

**Phone**

+98 21 8897 4707

**Fax**

+98 21 8897 4707

**Email**

info@tampouya.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tam Pouya Consulting & Research Company

**Full name of responsible person**

Motahareh Moafi

**Position**

Office worker

**Latest degree**

Bachelor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Unit 1, No. 1, Crot Building, Jahan mehr Street, Shahid  
Gomnam Street, Fatemi Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1431653941

**Phone**

+98 21 8897 4707

**Fax**

+98 21 8897 4707

**Email**

info@tampouya.com

**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