

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Fasted-state in vivo bioequivalence study of Gliclazide 60 mg sustained release tablet manufactured by AaniDarman compared with innovator product

#### Protocol summary

##### Study aim

In vivo fasted-state bioequivalence study of Gliclazide 60 mg tablet

##### Design

The clinical trial has control and test groups with crossover, randomized design, without blinding. Twenty-four healthy male volunteers will participate randomly in the study as two twelve-person study groups. To randomly assign participants in two groups, the lottery method will be used.

##### Settings and conduct

After oral administration of 60 mg tablet to volunteer, the blood samples will be collected in predetermined time intervals up to 72 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation. Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation. Therefore, each volunteer will be his own "Control". The concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector. The study will be performed in Faculty of Pharmacy, Tabriz University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old) Exclusion criteria: Smoking, History of cardiovascular, liver and kidney disease, Pregnancy, Alcohol and drug addiction, History of drug allergy.

##### Intervention groups

Intervention group will receive a single oral dose of test drug product (Gliclazide 60 mg tablet manufactured by AaniDarman, Iran) and Control group will receive a single dose of reference drug product (Gliclazide 60 mg tablet manufactured in France). Blood samples will be taken for 72 hours at the mentioned time points after drug

administration and the plasma will be stored in freezer until analysis. In both groups, breakfast and lunch will be served two and six hours after drug administration, respectively.

##### Main outcome variables

Drug plasma concentration

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210519051345N43**

Registration date: **2024-01-17, 1402/10/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-01-17, 1402/10/27**

Update count: **0**

##### Registration date

2024-01-17, 1402/10/27

##### Registrant information

##### Name

Parvin Zakeri-Milani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 8801

##### Email address

pzakeri@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-10, 1402/10/20

##### Expected recruitment end date

2024-11-20, 1403/08/30

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Fasted-state in vivo bioequivalence study of Gliclazide 60 mg sustained release tablet manufactured by AaniDarman compared with innovator product

**Public title**  
Bioequivalence study of Gliclazide 60 mg tablet

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
General Health (in terms of Liver, Heart and Kidney) Age (18-59 years)  
**Exclusion criteria:**  
Smoking History of cardiovascular disease, liver and kidney disease Pregnancy Alcohol and drug addiction History of drug allergy

**Age**  
From **18 years** old to **59 years** old

**Gender**  
Both

**Phase**  
Bioequivalence

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **24**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up 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 and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.

**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**  
Biomedical Research Committee, Tabriz University of Medical Sciences  
**Street address**  
No.2 Central Building 3rd Floor, Tabriz University of Medical Sciences, Daneshgah st.  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
51664-14766  
**Approval date**  
2023-12-18, 1402/09/27  
**Ethics committee reference number**  
IR.TBZMED..REC.1402.701

## Health conditions studied

1

**Description of health condition studied**  
In the present study, the products will be administered to healthy volunteers

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

1

**Description**  
Plasma concentration of drug

**Timepoint**  
0.5-72 hours in predetermined time intervals after drug administration

**Method of measurement**  
HPLC (High performance liquid chromatography)

## Secondary outcomes

empty

## Intervention groups

1

**Description**  
Intervention group: Intervention group will receive a single oral dose of test product (Gliclazide 60 mg tablet manufactured by AaniDarman, Iran) in fasted state. Blood samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively

**Category**  
Treatment - Drugs

## 2

### Description

Control group: Control group will receive a single oral dose of reference product (Gliclazide 60 mg tablet manufactured in France) in fasted state. Blood samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be stored in freezer until analysis. Breakfast and lunch will be served two and six hours after drug administration, respectively.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Pharmacy, Tabriz University of Medical Sciences

##### Full name of responsible person

Parvin Zakeri-Milani

##### Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

51664-14766

##### Phone

+98 41 3334 8801

##### Email

pzakeri@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Parviz Shahabi

##### Street address

No.2 Central Building 3rd Floor, Tabriz University of Medical Science, Daneshgah st.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

51664-14766

##### Phone

+98 41 3334 8801

##### Email

shahabip@tbzmed.ac.ir

##### Grant name

##### Grant code / Reference number

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

No

### Title of funding source

AaniDarman 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Parvin Zakeri-Milani

#### Position

Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.

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#### Province

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Parvin Zakeri-Milani

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Professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Parvin Zakeri-Milani  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaboori st., Golgasht st.  
**City**  
Tabriz

## 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

Not applicable

### 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

Not applicable

### Data Dictionary

Not applicable