

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### The investigation of the therapeutic effects of Piacidin capsule in patients with type 2 diabetes mellitus: a double-blind study

#### Protocol summary

##### Study aim

The investigation of the therapeutic effects of Piacidin capsule in patients with type 2 diabetes mellitus: a double-blind study

##### Design

In the present study, the sample size will include 66 patients who will be divided into two groups, placebo and treatment (33 patients in each group). Piacidin capsules will be prescribed once/day for three months.

##### Settings and conduct

Patients with type 2 diabetes will be included from Baqiyatullah Hospital, Tehran, Iran. Sixty-six diabetic patients were randomly divided into two groups of 33 patients: placebo and piacidin capsule groups. Piacidin and placebo (300 mg) capsules will be prescribed once a day for three months for both groups. In addition, patients and the person who evaluating the results will not be aware of the status of their assignment to the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The blood triglyceride level should be between 150 and 500 mg/dL. HbA1c level should be less than 8.5%. Patients should not change their blood sugar-lowering drug regimen. Patients should not have systemic diseases. Exclusion criteria: Uncontrollable blood pressure- Pregnancy or breastfeeding- Mental and psychological disorders- Addiction - Hyperthyroidism

##### Intervention groups

In the present study, sixty-six diabetic patients will be randomly divided into two groups of 33 people, placebo and treatment. Placebo capsules and piacidin capsules (300 mg) will be prescribed once/day for three months for the treatment group. The placebo group will be prescribed a capsule similar to the original capsule daily for 3 months.

##### Main outcome variables

HbA1c; FBS ; serum concentration of nitric oxide; serum concentration of lipids; insulin resistance; Serum levels of glutathione and malondialdehyde

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110614006804N3**

Registration date: **2024-01-23, 1402/11/03**

Registration timing: **prospective**

Last update: **2024-01-23, 1402/11/03**

Update count: **0**

##### Registration date

2024-01-23, 1402/11/03

##### Registrant information

##### Name

Mohammad Javad Behzadnia

##### Name of organization / entity

Baghyatallah medical sciences university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8126 2012

##### Email address

behzadnia@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-20, 1402/12/01

##### Expected recruitment end date

2024-08-22, 1403/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The investigation of the therapeutic effects of Piacidin capsule in patients with type 2 diabetes mellitus: a double-blind study

## Public title

The effects of Piacidin in treatment of diabetes

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

1- Blood triglyceride level should be between 150 and 500 mg/dL. 2- HbA1c level should be less than 8.5%. 3- The age of patients should be between 30 and 65 years. 4- Patients should not make any changes in their blood sugar lowering drug regimen or their physical activity. 5- Patients should not have systemic diseases or malignancy or chronic kidney or liver diseases.

### Exclusion criteria:

## Age

From **30 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **66**

More than 1 sample in each individual

Number of samples in each individual: **2**

The patients' blood samples will be taken twice (once before the start of the treatment and the second time, three months after the Piacidin capsule administration).

## Randomization (investigator's opinion)

Randomized

## Randomization description

First, piacidin and placebo capsules will be prepared in the same packaging and appearance and size. Then, they are coded based on the codes already prepared using random numbers table. Randomization method: Permuted block randomization is done so that first all blocks of size 4 containing two codes A and B are prepared and then random blocks are selected by placement using random numbers table (17 blocks). Each of codes is randomly assigned to one of the groups. The list of codes for each drug will remain with one of the executors until the end of the study. Numerical codes from 1 to 66 are recorded on drugs, and patients receive drug no. 1 to 66 after entering the study, respectively.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In the present study, patients will be divided into treatment and placebo groups. The treatment group will receive piacidin capsule. The placebo group will receive placebo capsule; which is similar in color, shape and size to the piacidin capsule. First, we explain to the patients that they will receive one of the two treatments, piacidin or placebo, randomly. Patients are put in group A or B.

According to this, one of the drugs that are completely identical in appearance and only tagged as A, B will be prescribed for him/her. Participants (diabetic patients) and Outcome assessor will be blinded.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Baqiyatallah hospital

##### Street address

Trauma Research Center; Baqiyatallah University of Medical Sciences; Nosrati alley; Sheikh Bahaie street; Molla Sadra street; Vanaq square

##### City

Tehran

##### Province

Tehran

##### Postal code

1435916471

#### Approval date

2023-12-11, 1402/09/20

#### Ethics committee reference number

IR.BMSU.BAQ.REC.1402.085

## Health conditions studied

### 1

#### Description of health condition studied

type 2 diabetes mellitus

#### ICD-10 code

Type 2 dia

#### ICD-10 code description

E11

## Primary outcomes

### 1

#### Description

Quantitative measurement of serum nitric Oxide, glutathione and malondialdehyde levels, blood sugar and lipid levels

#### Timepoint

before drug administration (day 0) and 3 month after drug administration (day 90)

#### Method of measurement

Oxidative stress and nitric oxide serum levels will be measured using specific biochemical kits, blood sugar and lipids variables will be assessed based on individual

laboratory sample results.

## Secondary outcomes

1

### Description

none applicable

### Timepoint

none applicable

### Method of measurement

none applicable

## Intervention groups

1

### Description

Intervention group: Includes diabetic patients who receive piacidin capsules (300 mg).

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Baqiyatallah hospital

#### Full name of responsible person

Mohammad Javad Behzadnia

#### Street address

Baqiyatallah hospital, Nosrati alley, Sheikh Bahaie street, Molla Sadra street, Vanaq square

#### City

Tehran

#### Province

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#### Postal code

1435916471

#### Phone

+98 21 8126 2012

#### Email

behzadnia@bmsu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

Bagheiat-allah University of Medical Sciences

#### Street address

Baqiyatallah University of Medical Sciences; Nosrati alley; Sheikh Bahaie street; Molla Sadra street; Vanaq squar

#### City

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### Province

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### Email

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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

Bagheiat-allah University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

Mohammad Javad Behzadnia

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Emergency Medicine

#### Street address

Emergency department, Baghyatallah Hospital, Nosrati alley, Sheikh Bahaie street, Molla Sadra street, Vanaq square

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Bagheiat-allah University of Medical Sciences

#### Full name of responsible person

Mohammad Javad Behzadnia

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is shareable after de-identifying individuals.

**When the data will become available and for how long**

After publication of article

**To whom data/document is available**

For academic and scientific researchers and institutions

**Under which criteria data/document could be used**

After researcher's request assessment, it could be possible for sharing the data.

**From where data/document is obtainable**

Via the corresponding author of the research.

**What processes are involved for a request to access data/document**

First of all a requesting email should send for the corresponding author; after the confirmation of the sender identity and his/her goal, we could share the data.

**Comments**