

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### The Effect of Metformin on Erectile Dysfunction in Male Patients with Type 2 Diabetes Mellitus

#### Protocol summary

##### Study aim

Evaluation of the effect of Metformin on erectile dysfunction in male patients with type 2 diabetes mellitus

##### Design

A double-blind randomized clinical trial, group controlled, on 270 patients, randomized by Excel software.

##### Settings and conduct

This randomized double-blind clinical trial will be conducted on 270 cases of men between the ages of 30 and 70 who were recently diagnosed with type 2 diabetes mellitus during a visit to the Loghman Hakim Hospital clinic in Tehran. Patients will be randomly assigned to two groups. Intervention group receives dietary advice and Metformin, and control group receives dietary advice and placebo. All subjects will be followed up for 3 months. The investigation of erectile dysfunction will be done using the International Index of Erectile Function (IIEF) questionnaire. Also, serum levels of testosterone, LH and FSH will be measured before and after the study.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Men aged 30 to 70 with newly diagnosed type 2 diabetes whose HbA1c level was between 6.5 and 8 in the last six months. Exclusion Criteria: History of diabetes or treatment with blood sugar control drugs, anatomical disorders in the penis or other sexual disorders, spinal cord injuries, stroke, heart attack in the last 6 months, treatment with mineral nitrates, peptic ulcer, migraine, visual impairment, allergic rhinitis

##### Intervention groups

Patients are randomly divided into two groups. In addition to prescribing a special diet, Metformin 500 mg tablets are used in the intervention group, once daily for 3 months, and in the control group, placebo tablets containing oral maltodextrin are used once daily for 3 months.

##### Main outcome variables

erectile dysfunction status; testosterone serum level; luteinizing hormone serum level; follicle-stimulating hormone serum level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221120056553N2**

Registration date: **2023-02-03, 1401/11/14**

Registration timing: **retrospective**

Last update: **2023-02-03, 1401/11/14**

Update count: **0**

##### Registration date

2023-02-03, 1401/11/14

##### Registrant information

##### Name

Saeid Kalbasi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5102 5582

##### Email address

saeidkalbasi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2021-06-20, 1400/03/30

##### Actual recruitment start date

2020-12-21, 1399/10/01

##### Actual recruitment end date

2021-06-20, 1400/03/30  
**Trial completion date**  
2021-09-23, 1400/07/01

**Scientific title**  
The Effect of Metformin on Erectile Dysfunction in Male Patients with Type 2 Diabetes Mellitus

**Public title**  
Metformin in Erectile Dysfunction of Diabetic Men

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Men between 30 and 70 years of age who have recently been diagnosed with type 2 diabetes during a visit to the Loqman Hakim Hospital clinic Patients whose HbA1c levels were between 6.5 and 8 in the last six months

**Exclusion criteria:**  
Patients with a history of diabetes or those who are being treated with blood sugar control drugs Patients who have anatomical disorders in the penis or other sexual disorders Patients with spinal cord injuries Patients who have a stroke Patients who experienced cardiac attack in the past six months Patients who are being treated with mineral nitrates Patients who have peptic ulcers Patients who have migraine Patients who have visual impairment Patients who have allergic rhinitis

**Age**  
From **30 years** old to **70 years** old

**Gender**  
Male

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **270**  
Actual sample size reached: **270**

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

**Randomization description**  
Random sequence generation will be done by simple randomization and preparing and shuffling cards, so that 270 cards (135 cards with the symbol A and 135 cards with the symbol B) will be prepared and will be placed inside Sequentially Numbered Opaque Sealed Envelops (SNOSE) and will be shuffled. According to arrival eligible patients will choose an envelope, so that the relevant group is determined (patients will be unaware of each other's assigned group). The selected envelope will be separated from the rest of the envelopes. This process will be continued until the 270th patient, so that finally 135 patients will be placed in the intervention group and 135 patients in the placebo group.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

In this study, patients, clinical caregivers and doctors, the main researcher and the outcome assessor will be unaware of the type of medication the patient is taking (Metformin or placebo) and the medication will be delivered to the patient by a nurse.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti of Medical Sciences

**Street address**

Yaman Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2020-12-15, 1399/09/25

**Ethics committee reference number**

IR.SBMU.MSP.REC.1399.507

**Health conditions studied**

1

**Description of health condition studied**

Type 2 Diabetes Mellitus

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

2

**Description of health condition studied**

Erectile Dysfunction

**ICD-10 code**

N52

**ICD-10 code description**

Male erectile dysfunction

3

**Description of health condition studied**

Erectile Dysfunction

**ICD-10 code**

F52.21

## ICD-10 code description

Male erectile disorder

## Primary outcomes

### 1

#### Description

Status of erectile dysfunction

#### Timepoint

Before the study and 90 days after the intervention

#### Method of measurement

The International Index of Erectile Function questionnaire

## Secondary outcomes

### 1

#### Description

Body weight

#### Timepoint

Before the study and 90 days after the intervention

#### Method of measurement

Body weight scale

### 2

#### Description

Body mass index

#### Timepoint

Before the study and 90 days after the intervention

#### Method of measurement

Calculator

### 3

#### Description

Systolic blood pressure

#### Timepoint

Before the study and 90 days after the intervention

#### Method of measurement

Mercury pressure gauge

### 4

#### Description

Diastolic blood pressure

#### Timepoint

Before the study and 90 days after the intervention

#### Method of measurement

Mercury pressure gauge

### 5

#### Description

Glycated hemoglobin A1c

#### Timepoint

Before the study and 90 days after the intervention

#### Method of measurement

Chromatography

### 6

#### Description

Fasting Blood Sugar

#### Timepoint

Before the study and 90 days after intervention

#### Method of measurement

Photometric method auto analyzer

### 7

#### Description

Testosterone Serum Level

#### Timepoint

Before the study and 90 days after the intervention

#### Method of measurement

ELISA Kit

### 8

#### Description

Luteinizing hormone Serum Level

#### Timepoint

Before the study and 90 days after the intervention

#### Method of measurement

ELISA Kit

### 9

#### Description

Follicle-Stimulating Hormone Serum Level

#### Timepoint

Before the study and 90 days after the intervention

#### Method of measurement

ELISA Kit

## Intervention groups

### 1

#### Description

Intervention group: Patients in this group are prescribed 500 mg metformin tablets, one daily for 3 months. According to the duration of the study, 90 tablets are prepared for each person. Patients will be advised to take the medicine with food to reduce digestive side effects.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The patients of this group will be given a placebo pill containing oral maltodextrin, one daily for three months. Placebo is completely similar to Metformin in the shape and size of the package. According to the duration of the study, 90 tablets are prepared for each person.

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Loghman e Hakim Hospital  
**Full name of responsible person**  
Saeid Kalbasi  
**Street address**  
South Kargar  
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Lcrdc@sbmu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Afshin Zarghi  
**Street address**  
Shahid Arabi Ave  
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info@sbmu.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti University of Medical Sciences  
**Proportion provided by this source**  
50  
**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**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Hooriyeh Talati  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Internal Medicine  
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Yaman Ave  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Hooriyeh Talati  
**Position**  
Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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Yaman Ave

**City**

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**Province**

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**Postal code**

1985717443

**Phone**

+98 21 5102 5582

**Email**

hoota\_69734@yahoo.com

**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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

The data spss file includes groups and main and demographic variables

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

After publication the article extracted from the plan

**To whom data/document is available**

Those who have corresponded with the author responsible for the plan and have enough reason to receive the file

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

We have not made a decision on this matter and a decision will be made after reviewing the request

**From where data/document is obtainable**

Endocrine and metabolic disease research center of Loghman -e Hakim hospital ,Shahid Beheshti medical science , Tehran Saeid Kalbasi  
email:saeidkalbasi@bums.ac.ir

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

The applicant should send her/him request via email and after obtaining permission from all project partners, if the partners agree with her request, the data will be sent to her/him.

**Comments**