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 been 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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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