Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of the effect of adding oral vial L-carnitine on the efficacy of sildenafil citrate tablets in the treatment of erectile dysfunction in men with type 2 diabetes

Protocol summary

Study aim
Determining the effect of adding oral vial L-carnitine on the efficacy of sildenafil citrate tablets in the treatment of erectile dysfunction in men with type 2 diabetes

Design
This study is a double-blind randomized clinical trial with parallel groups that is performed in phase 3 clinical trial on 40 diabetic patients with erectile dysfunction. For randomization in this study, block randomization method with proportional number and software was performed.

Settings and conduct
This study is performed in 40 diabetic patients with erectile dysfunction in Imam Reza Clinic in Arak. Patients are not aware of the type of medication they are taking and For the control group, an oral L-carnitine placebo vial made by the same company was used. Also the intern in charge of the project who is responsible for filling out the questionnaire; He is not aware of the type of groups according to the drug used and only recognizes the groups based on A and B, and the form of demographic information and the International Erectile Dysfunction Questionnaire 5 (IIEF5) are completed for both groups. 4 weeks later, patients' erectile function will be evaluated again.

Participants/Inclusion and exclusion criteria
Erectile dysfunction; diagnosis of type 2 diabetes; age 40 to 70 years old; no spinal cord injury

Intervention groups
In the intervention group, sildenafil citrate tablets in the amount of 100 mg half an hour before sexual intercourse with oral vial of carnitine alone or dissolved in a drink or liquid food at a rate of 1 g per day is used and the second group (control group) will also be treated with sildenafil citrate 100 mg half an hour before each sexual intercourse with an oral placebo vial. After 4 weeks, the International Erectile Dysfunction Questionnaire 5 (IIEF5) will be completed again in similar circumstances.

Main outcome variables
Erectile function

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200714048106N1**
Registration date: **2020-07-29, 1399/05/08**
Registration timing: **prospective**

Last update: **2020-07-29, 1399/05/08**
Update count: **0**

Registration date
2020-07-29, 1399/05/08

Registrant information
Name
Hesam-o-din Rezaee
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-21, 1400/02/01
Expected recruitment end date
2021-06-21, 1400/03/31
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adding oral vial L-carnitine on the efficacy of sildenafil citrate tablets in the treatment of erectile dysfunction in men with type 2 diabetes

Public title

The effect of L-carnitine on erectile dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Erectile dysfunction Diagnose type 2 diabetes for at least three months No history of taking sildenafil citrate or L-carnitine during the previous three months

Exclusion criteria:

Patients with spinal cord injury Patients treated with sildenafil citrate or L-carnitine. Severe kidney failure Known liver disease Erectile dysfunction (ED) with known and treated origin of psychological disorder

Age

From **40 years** old to **70 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 40 male patients with type 2 diabetes referred to Imam Reza (AS) Diabetes Clinic who complain of erectile dysfunction and this disorder has been approved by a urologist who collaborated with the project, if they have the conditions to enter the study and Using block randomization method and using software are divided into two groups of intervention and control

Blinding (investigator's opinion)

Double blinded

Blinding description

Blindness, due to its double blindness, is such that in this study, only the specialist in charge of the study is aware of the type of study and the study groups, while patients are not aware of the type of drug used. Also, the intern in charge of the project who is responsible for filling out the questionnaire; He is not aware of the type of groups according to the drug used and only recognizes the groups based on A and B, and the form of demographic information and the International Erectile Dysfunction Questionnaire 5 (IIEF5) are completed for both groups. Patients are randomly divided into intervention and control groups, and both groups receive sildenafil tablets, but the intervention group receives vials of L-carnitine and the placebo control group receives the same vial of L-carnitine, both of which are manufactured by BSK Bio-Fermentation. .receive sildenafil tablets, but the intervention group is vial L-carnitine and the placebo control group is similar to vial L-carnitine, both of which are manufactured by B. They receive bio-fermentation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Payambar-e-azam Complex, Basij Sq., Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.ARAKMU.REC.1399.056

Health conditions studied

1

Description of health condition studied

Erectile dysfunction

ICD-10 code

N52

ICD-10 code description

Male erectile dysfunction

Primary outcomes

1

Description

Erectile function

Timepoint

After 4 weeks

Method of measurement

International index of erectile function 5 (IIEF5)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the form containing demographic information and the International Erection Questionnaire for patients are completed, and then they receive the sildenafil tablet in addition to the L-carnitine vial manufactured by BSKa Fermentation Company. Sildenafil Citrate 100 mg tablets half an hour before sexual intercourse with oral L-carnitine vial alone or dissolved in 1 g of liquid beverage or food (oral BSK vial of BSK brand made by Iran Bio Fermentation Company) in Consumed during the day. The study will continue for 4 weeks. After 4 weeks, the International Erectile Dysfunction Questionnaire 5 (IIEF5) will be completed again in similar conditions.

Category

Treatment - Drugs

2

Description

Control group: First, the form containing demographic information and the International Erection Questionnaire for patients was completed and patients treated with sildenafil citrate tablets at a dose of 100 mg half an hour before each sexual intercourse with an oral placebo vial with a drink (made by Iran Bio Fermentation Company). Will take. The study will continue for 4 weeks and after 4 weeks, the International Erectile Dysfunction Questionnaire 5 (IIEF5) will be completed again in similar conditions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza clinic

Full name of responsible person
Hesam-o-din Rezaie

Street address
Imam Reza Specialized and Sub-Specialized Clinic, Shahid Shiroudi St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Alireza Kamali

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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Hesam-o-din Rezae

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Hesam-o-din Rezae

Position

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Latest degree

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Other areas of specialty/work

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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

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

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

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

Data Dictionary

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