

# 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)

##### Phone

+98 25 1457 7848

##### Email address

hesameddinrezaei13740624@gmail.com

##### 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.

##### City

Arak

##### Province

Markazi

##### Postal code

3813899589

##### Phone

+98 86 2402 0021

##### Email

Imamrezaclinic@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Alireza Kamali

##### Street address

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

##### City

Arak

##### Province

Markazi

##### Postal code

3848176341

##### Phone

+98 86 3417 3639

##### Email

research@arakmu.ac.ir

#### 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

##### Street address

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

##### City

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##### Province

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##### Postal code

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##### Phone

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**Email**

hesameddinrezaei13740624@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**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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hesameddinrezaei13740624@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Hesam-o-din Rezae

**Position**

Student

**Latest degree**

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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