

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

The Effect of L-Arginine Supplementation on Hypogonadism in Patients with Diabetes Type 2.

Protocol summary

Study aim

Determining the Effect of L-Arginine Supplementation on Hypogonadism in Men with Type 2 Diabetes

Design

Clinical Trial with Control Group, Parallel Group, Double-Blind, Randomized, in which Patients will be Randomly divided into Two Equal Groups (n=25). Block Randomization Method (Quadruple Block) will be used for Randomization.

Settings and conduct

Controlled Clinical Trial, Parallel Group, in which Patients will be Randomly divided into Two Equal Groups. The Intervention Group will be given Oral L-Arginine and the Control Group will be given a Placebo. Patients will be divided in such a Way that only the Physician Treating the Patient's Diabetes is Aware of the Division and the Researcher and the Patient and the Statistical Expert are not Aware of the Division until the End of the Study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Erectile Dysfunction, Diabetes, HBA1C between 5.5 to 7, Age 40 to 60 Years; No Entry Conditions: Patients with Prostate cancer or Hyperplasia, Liver or Kidney Failure, Cardiopulmonary disease, Psychological disease

Intervention groups

The Intervention Group will be treated with Oral L-Arginine Supplement at a Rate of 3 Grams per Day (with BSK Brand made by Iran Zist Takhmir Company) and the Control Group will be treated with Placebo with Similar Form and Color of Drug (BSK Brand made by Iran Zist Takhmir Company).

Main outcome variables

Determining the Score of Erectile Dysfunction based on the International Questionnaire of Erectile Dysfunction 5, Free and Total Testosterone Serum Levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220112053700N1**

Registration date: **2022-02-12, 1400/11/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-12, 1400/11/23**

Update count: **0**

Registration date

2022-02-12, 1400/11/23

Registrant information

Name

Mohammad reza Naderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 4476

Email address

reza.naderi1988@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-12, 1400/11/23

Expected recruitment end date

2022-03-14, 1400/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of L-Arginine Supplementation on Hypogonadism in Patients with Diabetes Type 2.

Public title

The Effect of L-Arginine Supplementation on Hypogonadism in Patients with Diabetes Type 2.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male Gender Erectile Dysfunction (ED) for at Least 3 Months Having Type 2 Diabetes for at Least a Year Total Testosterone Levels Less than 8 nanomol /Liter or Serum Testosterone in the Range of 8 to 11 nanomol /Liter and Free Testosterone Levels Less than 220 picomoles /Liter Age 40 to 60 Years HBA1C Between 5.5 and 7 (Low and Moderate Risk Diabetes) Do not Take Exogenous Anabolic Steroids

Exclusion criteria:

Patients with Erectile Dysfunction (ED) of known Psychological Origin Patients with Prostate Cancer or Benign Prostatic Hyperplasia Patients with a History of Sleep Apnea Patients with Spinal Cord Injury Patients with known and treated Cardiopulmonary Injury Patients with Hyperthyroidism or Hypothyroidism Patients with known Liver Failure Patients with known Renal Failure Patients with a History of Seizures Patients with known Microvascular Complications of Diabetes (Retinopathy, Neuropathy, Nephropathy Taking Anti-Libido Drugs Taking Antipsychotic or Mood Stabilizing or Antidepressant Medications

Age

From **40 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be Randomly Assigned to Groups A and B by Block Randomization (Quadruple Block). Due to Having Two Intervention and Control Groups, in each Block, There should be an Equal Number of Modes A and B, which According to the Volume of the Four Blocks, there will be Six Different Modes for the Blocks, which are: AABB, ABAB, ABBA BBAA, BABA, BAAB. Different States of the Blocks will be written on Cardboard Cards of the Same Size and Color. According to the Sample Size (50 Patients) and Five Modes of Blocks, 10 Times the Cards were Randomly Selected by Replacing and Selecting the Blocks, Determining the order of Placing Patients in Groups A (Control) and B (Intervention) will do And According to the Sample Size, the Patients with the Inclusion Criteria will be divided in such a way that only

the physician treating the patient's diabetes is aware of the division and the researcher (student) and the Patient and the Statistical Expert are not Aware of the Division until the end of the Study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Eligible Patients will be Divided in such a way that only the Physician Treating the Patient's Diabetes is Aware of the Classification and the Researcher (Student) and the Patient and the Statistical Expert are not Aware of the Classification until the end of the Study.

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

No.31, Mahdie St., Imam Khomeini St

City

Arak

Province

Markazi

Postal code

3814955756

Approval date

2022-01-16, 1400/10/26

Ethics committee reference number

IR.ARAKMU.REC.1400.294

Health conditions studied

1

Description of health condition studied

Diabetes Type 2

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Percentage of Individuals with the International Index of Erectile Function-5 Questionnaire Score of Less than 21

Timepoint

Filling in the Questionnaire at the Beginning of the Study and 8 Weeks after Taking L-Arginine Supplement or Placebo

Method of measurement

The International Index of Erectile Function-5

2

Description

Free and Total Testosterone Serum Levels

Timepoint

Measurement of Free and Total Testosterone Serum Levels at the Beginning of the Study and 8 Weeks after Taking L-Arginine Supplement or Placebo

Method of measurement

Laboratory Kit by ELISA Method

Secondary outcomes

1

Description

Fasting Blood Sugar

Timepoint

Measurement of Fasting Blood Sugar Levels at the Beginning of the Study and 8 Weeks after Taking L-Arginine Supplement or Placebo

Method of measurement

Laboratory Kit by ELISA Method

2

Description

Hemoglobin A1C

Timepoint

Measurement of Hemoglobin A1C Levels at the Beginning of the Study and 8 Weeks after Taking L-Arginine Supplement or Placebo

Method of measurement

Laboratory Kit by ELISA Method

Intervention groups

1

Description

Intervention group: All Patients Selected from the Intervention Group Should be Treated with Oral L-Arginine Supplement Alone or dissolved in a Beverage or Liquid Food at a rate of 3 Gram per Day (Oral L-Arginine Vial with BSK Brand made by Iran Zist Takhmir Company) The will Continue for 8 Weeks and at the End of each Week the Method of Taking the Drug and Possible Complications and Problems will be Followed up by Phone.

Category

Treatment - Drugs

2

Description

Control group: All Patients in the Control Group will be

treated with a Placebo Vial and a Similar Shape and Colore of the Drug at the rate of 3Gram per Day(with BSK Brand made by Iran Zist Takhmir Company) and will be followed Exactly by the Intervention Group by a Student who does not know how to Assign Groups.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Diabetes Clinic

Full name of responsible person

Bahman Sadeghi

Street address

No.31, Mahdie St., Imam Khomeini St.

City

Arak

Province

Markazi

Postal code

3814955756

Phone

+98 86 3222 4476

Email

Reza.naderi1988@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Amir Almasi

Street address

No2.,Basij Square

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3313 6055

Email

modavem@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

Province

Markazi

Postal code

3814955756

Phone

+98 86 3222 4476

Email

Reza.naderi1988@yahoo.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Bahman Sadeghi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

No.31,Mahdie St.,Imam Khomeini St

City

Arak

Province

Markazi

Postal code

3814955756

Phone

+98 86 3222 4476

Email

Reza.naderi1988@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Bahman Sadeghi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

No.31,. Mahdie St., Imam Khomeini St

City

Arak

Province

Markazi

Postal code

3814955756

Phone

+98 86 3222 4476

Email

Reza.naderi1988@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Bahman Sadeghi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

Street address

No.31., Mahdie St., Imam Khomeini St

City

Arak

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the Privacy of the Information, Patient Information is kept Confidential by the Project Manager.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available