Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

The Effect of L-Arginine Supplementation on Hypogonadism in Patients witht 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 Tow 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)

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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 witht Diabetes Type 2.

Public title
The Effect of L-Arginine Supplementation on Hypogonadism in Patients witht 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 Suger

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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Amir Almasi

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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
Bahman Sadehgi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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