Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Effect of L.Argenine oral supplementation on sexual function in men with type 2 diabetes

Protocol summary

Summary
The objective of this study is to determine the Effect of L-Argenine supplementation on sexual function in men with type 2 diabetes. This is a double blind study. Considering the 10 percent of flux, the sample size is 80. Patients will be randomly assigned into 2 groups, intervention and control group. The intervention group will take 5 gr/day of L-Arginine and the control group will take 5 gr/day of Methyl Cellulose(as placebo) for 4 weeks. At the beginning and end of the study, patients will be examined in terms of sexual function through the international index of erectile function (IIEF) questionnaire.

General information

Acronym
Argenine
IRCT registration information
IRCT registration number: **IRCT2015050322076N1**
Registration date: **2015-08-04, 1394/05/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2015-08-04, 1394/05/13

Registrant information
Name
Mohammad Hassan Rouhani
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3668 5770
Email address
sm_rouhani@nutr.mui.ac.ir

Recruitment status
Recruitment complete
Funding source
Department of Health, Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date
2014-03-20, 1392/12/29
Expected recruitment end date
2015-08-12, 1394/05/21
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of L.Argenine oral supplementation on sexual function in men with type 2 diabetes

Public title
The effect of arginine on sexual function in men with diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: being married; patients with mild to moderate erectile dysfunction (according to the score 15 to 25 obtained from the questionnaire of international index of erectile function (IIEF)); age between 25 to 55 years; a minimum of 5 years experience in diabetes. exclusion criteria: unstable cardiovascular status (angina and heart attack experience); cancer chemotherapy; those how taking reduced medications and secretion of androgen; surgery in the pelvic or prostate area; lack of personal satisfaction to log in to study; insulin users; consumers of opium and any apparent disorders of the genital system by endocrinologist assumption.
Age

From **25 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences

Street address

Department of Health,Shahid Sadoughi University of Medical Sciences, Hesabi Blvd

City

yazd

Postal code

Approval date

2013-07-29, 1392/05/07

Ethics committee reference number

17/1/81417/پ

Health conditions studied

1

Description of health condition studied

sexual dysfunction

ICD-10 code

F52.0

ICD-10 code description

Lack or loss of sexual desire

Primary outcomes

1

Description

sexual function

Timepoint

Before intervention and 4 weeks after intervention

Method of measurement

IIEF Questionnaire

Secondary outcomes

1

Description

Concentration of total testosterone

Timepoint

Before the intervention and after completion of the intervention

Method of measurement

Laboratory method Radio Immuno assay

Intervention groups

1

Description

The intervention group will take five grams of oral l-arginine in a 5 grams package for 28 days.

Category

Treatment - Drugs

2

Description

The control group will take five grams of oral Methyl Cellulose in 5 grams packages for 28 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Dr Hasan Mozaffari Khosravi

Street address

Diabetes Center, Talare Honar alley, Bahonar square

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Hasan Mozaffari Khosravi

Street address

Department of Health, Alem square

City

yazd

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd Shahid Sadoughi University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Mosayeb Fallahi
Position
Student of MSc Health Sciences in Nutrition
Other areas of specialty/work
Street address
Graduate Units,Department of Health,Shahid Sadoughi University of Medical Sciences, Hesabi Blvd
City
yazd
Postal code
Phone
+98 35 3623 8505
Fax
Email
mosayebfalahy@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd Shahid Sadughi University of Medical Sciences
Full name of responsible person
Hasan Mozaffari Khosravi
Position
PhD in Nutritional Sciences
Other areas of specialty/work
Street address
Graduate Units,Department of Health,Shahid Sadoughi University of Medical Sciences, Hesabi Blvd
City
yazd
Postal code
Phone
+98 35 3623 8505
Fax
Email
MOZAFFARI.KH@GMAIL.COM
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Yazd Shahid Sadughi University of Medical Sciences
Full name of responsible person
Mosayeb Fallahi
Position
Student of MSc Health Sciences in Nutrition
Other areas of specialty/work
Street address
Graduate Units,Department of Health,Shahid Sadoughi University of Medical Sciences, Hesabi Blvd
City
yazd
Postal code
Phone
+98 35 3623 8505
Fax
Email
mosayebfalahy@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty