Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Evaluating the effect of L-arginine on sexual function in women with depression

Protocol summary

Study aim
The effect of L-arginine on sexual function in women with depression

Design
A randomized clinical trial with blinded parallel groups, on 40 patients who are divided into two groups of 20 people.

Settings and conduct
Evaluating the effectiveness of L-arginine in the sexual performance of depressed women treated with selective serotonin reuptake inhibitor drugs. The place of study is Ayatollah Taleghani and Imam Hossein hospitals in Tehran. Placebo and L-arginine are prescribed to the patient by the clinical caregiver in similar coded containers for 8 weeks. The patient and the clinical caregiver do not know the type of intervention prescribed (placebo or L-arginine).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients in the age group of 18-60 years diagnosed with major depressive disorder by a physician according to the DSM-5 diagnostic criteria. Patients must be willing to enter the study and have not been treated with antidepressants in the past month. Patients have no autonomic disorders in the genital tract and can take oral medications, have no active gastrointestinal ulcers, and are married. Exclusion criteria: Patients with impaired blood pressure regulation, recent heart attack, major psychological disorders, alcohol consumption, stimulants, and drugs, as well as diabetes. Also, nitrate-based drugs, potassium-sparing drugs, phosphodiesterase five inhibitors, alpha two antagonists, cyproheptadine, and yohimbine. Women should not have menopause, and their marital relationships should be stable.

Intervention groups
Intervention group: receiving L-arginine with a total dose of 2 grams daily for 8 weeks. Placebo group: receiving placebo. L-arginine and placebo have been purchased from Jalinous Pharmaceutical Company in Iran.

Main outcome variables
sexual function; depression

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20100127003210N26**
Registration date: **2022-10-28, 1401/08/06**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-28, 1401/08/06**
Update count: **0**

Registration date
2022-10-28, 1401/08/06

Registrant information

Name
Maria Tavakoli Ardakani

Name of organization / entity
Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 8887 3704

Email address
mariatavakoli@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-06, 1401/06/15

Expected recruitment end date
2023-09-06, 1402/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of L-arginine on sexual function in women with depression

Public title
The effect of L-arginine on sexual function and depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients in the age group of 18-60 years. Patients are referred to the psychiatric clinic of Taleqani Hospital and Imam Hossein Hospital. Patients who are diagnosed with major depressive disorder by the DSM-5 diagnostic criteria. Patients who have the consent to enter the study and complete the consent form. Patients who have not had a history of taking an antidepressant in the past month before starting current medications. Patients who do not have autonomic disorders in the genital tract. Patients who can take oral medications and also likely to complete evaluations. Patients without active ulcers in the gastrointestinal tract. People entering the study must be married during the study period.
Exclusion criteria:
Patients who have impaired blood pressure regulation and are taking nitrate-based medications. Patients with diabetes mellitus Patients are taking potassium-sparing drugs. Patients are taking drugs that affect sexual dysfunction and improvement. Patients who have recently had a heart attack. Diagnosis of other psychological disorders along with the diagnosis of major depressive disorder or depression with anxiety in the patient. Consumption of alcohol or drugs or stimulants. Women who are in a menopausal state when starting the study. Lack of access or possibility of sexual intercourse with the husband during the study period.
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization. Patients are divided into 10 blocks of 4 individuals, and different interventions are performed for patients based on the type of group (placebo or intervention). Each category will be assigned a code, and based on that code, the medicine or placebo code will be presented to the participants, and the performer is unaware of the code assigned to the medicine or placebo. In this method, Sealed Envelope software with the following internet address is used. This site is a free site for randomization in clinical trials. https://www.sealedenvelope.com/
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo and L-arginine are prescribed to the patient in similar opaque containers by the clinical caregiver participating in the study. Placebo and L-arginine containers have been coded by the principal investigator prior to drug administration. The patient and clinical caregiver participating in the study do not know the type of compounds in the containers, as well as the codes assigned to placebo and L-arginine.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Faculty of Pharmacy - Shahid Beheshti University of Medical Sciences
Street address
Faculty of Pharmacy, Shahid Beheshti University of Medical Science, Valiasr St, Hashemi Rafsanjani Highway intersection, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2022-08-09, 1401/05/18
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.096

Health conditions studied

1

Description of health condition studied
Women's sexual function.
ICD-10 code
R68.82
ICD-10 code description
Decreased libido

2

Description of health condition studied
Depression
ICD-10 code
F32
ICD-10 code description
Major depressive disorder, single episode

Primary outcomes

1

Description
Sexual function of women
Timepoint
Four weeks before the intervention; Zero, four, and eight weeks after receiving L-arginine
Method of measurement
Rosen et al. questionnaire was used to assess sexual satisfaction for women.

Secondary outcomes

1

Description
side effects caused by using L-arginine
Timepoint
In two time periods of four and eight weeks after receiving L-arginine
Method of measurement
The patient complaint, clinical evidence, and symptoms

2

Description
Depression
Timepoint
In three time periods of zero, four and eight weeks after receiving L-arginine
Method of measurement
Hamilton questionnaire

Intervention groups

1

Description
Intervention group: receiving L-arginine tablets (produced by Jalinous Pharmaceutical Company) 2 grams per day for 8 weeks.
Category
Treatment - Drugs

2

Description
Placebo group: receiving placebo tablets (produced by Jalinous Pharmaceutical Company) for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleqani Hospital
Full name of responsible person
Maria Tavakoli Ardakani
Street address
Taleqani Hospital, Arabi Street, Daneshjoo Boulevard
City
Tehran
Province
Tehran
Postal code
1469658843
Phone
+98 21 2303 1111
Fax
Email
Taleghani@sbmu.ac.ir
Web page address
https://Taleghani.sbmu.ac.ir

2

Recruitment center
Name of recruitment center
Department of Psychiatry, Imam Hossein Hospital
Full name of responsible person
Jamal Shams
Street address
Imam Hossein Hospital, Shahid Madani Street, Imam Hossein Square.
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
info@ehmc.ir
Web page address
https://www.ehmc.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Fifth Floor, Building No 2, Shahid Arabi St, Yemen St, Shahid Chamran Highway, Tehran,
City
tehran

Province
Tehran
Postal code
1469658843
Phone
+98 21 2243 9780
Email
Info@sbmu.ac.ir
Web page address
https://sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maria Tavakoli Ardakani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid Beheshti School of Pharmacy, Niayesh Highway, Valiasr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1469658843
Phone
+98 21 8887 3704
Fax
+98 21 8887 3704
Email
Mariatavakoli@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Maria Tavakoli Ardakani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Valiasr St, Hashemi Rafsanjani Highway , Shahid Beheshti School of Pharmacy.
City
Tehran
Province
Tehran
Postal code
1469658843
Phone
+98 21 8887 3704
Email
Mariatavakoli@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Pouria Torkaman
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid Beheshti Faculty of Pharmacy, Niayesh educational complex, Valiasr intersection.
City
Tehran
Province
Tehran
Postal code
1465884332
Phone
+98 21 4445 4374
Email
pouriatorkamanofficial@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Therapeutic findings of the intervention can be shared by statistical analysis without providing patient names.

When the data will become available and for how long

Start 6 months after publication

To whom data/document is available

Physicians and other researchers involved in studies on sexual function and depression.

Under which criteria data/document could be used

People such as hospital staff or other medical staff such as nurses and clinical pharmacists can use this information.

From where data/document is obtainable

Researchers can contact us via email at: pouriatorkamanofficial@gmail.com.

What processes are involved for a request to access data/document

People who intend to use the information must be affiliated with reliable organizations and their requests should be submitted through these organizations. In this context, there is a need for an introduction letter from the desired center.

Comments