Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the effect of herbal combination of fenugreek seeds and carrot seeds on sexual function of women with diabetes type 2,a randomized double-blinded clinical trial

Protocol summary

Study aim

Evaluation of the effect of herbal combination of fenugreek seeds and carrot seeds on sexual function in women with diabetes type 2

Design

Two arm parallel groups randomized clinical trial, double blinded, phase 2 on 100 patients

Settings and conduct

Diabetic women aged 25-55 referred to health and medical centers of Kashan University of Medical Sciences who have sexual dysfunction are referred to the researcher.

Participants/Inclusion and exclusion criteria

Including Criteria 1. Married women with type 2 diabetes and sexual dysfunction 2. HBA1C between 7.1 & 8.5 3. Age between 25 & 55 years Excluding criteria 1. Diagnosis of current chronic diseases affecting sexual function in the patient or his wife during the study 2. taking drugs that affect sexual function 3. The occurrence of an unfortunate incident such as the loss of partner or close relative during the study 5. Getting pregnant 6. Menopause

Intervention groups

The intervention group received 500 mg tablets of herbal combination three times a day for 8 weeks and the placebo group received placebo tablets with the same order. During this period, patients are followed up by telephone once a week regarding the correct use of medicine and possible side effects. After entering the study, patients are visited after 4 weeks and at the end of 2 months.

Main outcome variables

At the beginning and end of the study, Questionnaire of the Women's Sexual Performance Index (FSFI), Global Sexual Satisfaction Scale (GMSEX) and General Health Questionnaire (GHQ-12) will be filled, and the tests will include fasting blood sugar (FBS), two hours postprandial blood sugar (2PPBS).hemoglobin A1C will be repeated and possible drug side effects will be recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050457N2**
Registration date: **2023-05-08, 1402/02/18**
Registration timing: **prospective**

Last update: **2023-05-08, 1402/02/18**
Update count: **0**

Registration date

2023-05-08, 1402/02/18

Registrant information

Name

Fatemeh Shirvanizade arani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5472 5800

Email address

dr.shirvanizade@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-31, 1402/03/10

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of herbal combination of fenugreek seeds and carrot seeds on sexual function of women with diabetes type 2,a randomized double-blinded clinical trial

Public title

Evaluation of the effect of herbal combination of fenugreek seeds and carrot seeds on sexual function 0fwomen with diabetes type 2,a randomized double-blinded clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women with type 2 diabetes and sexual dysfunction HBA1C between 7.1 & 8.53. Age between 25 & 55 years diabetic patients should not have systemic diseases such as liver failure, kidney failure, heart failure, thyroid failure, central nervous system disorders, or retinopathy. Absence of pregnancy and breastfeeding Absence of Ovariectomy history and Ovarian agenesis Having a stable life with his wife Married for at least one year

Exclusion criteria:

Diagnosis of having chronic diseases affecting sexual function in the patient or his partner during the study (such as cardiovascular or mental or thyroid disorders, cancers) taking drugs that affect sexual performance The occurrence of an unfortunate incident such as the loss of partner or close relative during the study vaginal bleeding, dyspareunia, vaginismus Getting pregnant Menopause

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

People are randomly divided to drug and placebo groups. The drug group received 500 mg herbal tablets three times a day, and the placebo group received placebo tablets with the same prescription.

Blinding (investigator's opinion)

Double blinded

Blinding description

The intervention group received 500 mg herbal tablets three times a day, and the placebo group received placebo tablets with the same order.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Shahid Dr. Rahnamun Hospital, Yazd

Street address

Motahari Blvd., end of 1st Hekmat Alley

City

Aran and bidgol

Province

Isfehan

Postal code

8741646949

Approval date

2023-03-05, 1401/12/14

Ethics committee reference number

IR.SSU.SRH.REC.1401.026

Health conditions studied

1

Description of health condition studied

Type 2 diabetes with sexual dysfunction

ICD-10 code

E11.8

ICD-10 code description

Type 2 diabetes mellitus with unspecified complications

Primary outcomes

1

Description

Sexual function

Timepoint

At the beginning of the study and after two months of taking the drug

Method of measurement

Questionnaire

Secondary outcomes

1

Description

FBS

Timepoint

At the beginning of the study and 60 days after starting to take the drug

Method of measurement

Lab test

2

Description

2 hours post prandial blood sugar

Timepoint

At the beginning of the study and 60 days after starting to take the drug

Method of measurement

Lab test

3

Description

HB A1C

Timepoint

At the beginning of the study and 60 days after starting to take the drug

Method of measurement

Lab test

4

Description

Mental health

Timepoint

At the beginning of the study and 60 days after starting to take the drug

Method of measurement

questionare

Intervention groups

1

Description

The intervention group consumes 500 mg herbal tablets three times a day. The drug is prescribed to patients for 8 weeks by a non-researcher, based on masking. The raw materials of this product, which include carrot seeds and fenugreek seeds, are first subjected to quality control tests, including the amount of waste particles, moisture, total ash, and determining the amount of an indicator substance or total essential oil. After determining the quality of each plant, 250 mg of 5% fenugreek seed extract (Fenugreek seed extract) is mixed with 250 mg of carrot seed powder and then sieved and produced in the form of 500 mg tablets with a press machine.

Category

Treatment - Drugs

2

Description

The control group consumes 500 mg placebo tablets made of starch but with a completely similar appearance to the drug three times a day. The placebo is prescribed to patients for 8 weeks by a non-researcher.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes center of Aran & Bidgol and Kashan cities

Full name of responsible person

Fatemeh Shirvanizadeh Arani

Street address

Hekmat1 Alley, Motahari Blvd

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8741646949

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Email

dr.shirvanizade@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi AbarQoui

Street address

1st Hekmat Alley ,Motahari Blvd

City

Aran and bidgol

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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

Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Fatemeh shirvanizadeh Arani
Position
Phd student
Latest degree
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Traditional Medicine
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Person responsible for updating data

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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
The data will publish in the form of a thesis
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
For researchers working in academic and scientific institutions
Under which criteria data/document could be used
With an official letter from the Research and Technology Vice-Chancellor of Yazd University of Medical Sciences
From where data/document is obtainable
Fatemeh Shirvanizadeh, Faculty of Persian Medicine, Ardakan, Yazd
What processes are involved for a request to access data/document
Refer to the research and technology unit of Yazd University of Medical Sciences and ask for it
Comments