

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 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 of women 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

Isfahan

##### 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

**City**

Aran and bidgol,

**Province**

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**Postal code**

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**Phone**

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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

**Province**

Isfahan

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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**  
Fateme Shirvanizadeh Arani  
**Position**  
Phd student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Traditional Medicine  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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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 be published 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

Fateme 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