

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessing the effect of vitex agnus , fennel seed, and spearmint on improving female sexual and physical function

#### Protocol summary

Registration timing: **prospective**

##### Study aim

Assessing the effect of vitex agnus , fennel seed, and spearmint on improving female sexual and physical function

Last update: **2022-04-22, 1401/02/02**

Update count: **0**

##### Registration date

2022-04-22, 1401/02/02

##### Design

80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table

##### Registrant information

###### Name

soodeh razeghi Jahromi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6634 8500

###### Email address

razeghi@sina.tums.ac.ir

##### Settings and conduct

This double blinded study will be performed in private clinic. At base line and after 8 weeks of intervention with supplement/placebo, sexual function will be assessed using FSFI questionnaire.

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-50 years, reduced sexual desire according to sexual function index questionnaire (FSFI), Having satisfying sexual relationship with permanent and active partner for at least previous one year, Having sexual relationship at least once a month Exclusion criteria: Pregnancy and lactation, Delay in menstruation for 2 month or more, Having diabetes, Having known cardiovascular disease, Having known renal disease, Hypothyroid, Having any types of cancer

##### Expected recruitment start date

2022-05-05, 1401/02/15

##### Expected recruitment end date

2022-10-07, 1401/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Intervention groups

Patients will receive 500 mg Femexite (Ghaem Daro) capsule or placebo two times daily for 8 weeks. Each capsule contains vitex agnus , fennel seed, and spearmint or corn starch in placebo group.

##### Scientific title

Assessing the effect of vitex agnus , fennel seed, and spearmint on improving female sexual and physical function

##### Main outcome variables

sexual function index using FSFI questionnaire

##### Public title

the effect of Vitex agnus , fennel seed, and spearmint on

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140804018677N15**

Registration date: **2022-04-22, 1401/02/02**

improving female sexual and Physical function

## **Purpose**

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Age 18-50 years Decreased libido according to sexual function index questionnaire (FSFI) Having satisfying sexual relationship with permanent and active partner for at least one recent year Having sexual relationship at least once a month

### **Exclusion criteria:**

Pregnancy and lactation Delay in menstruation for 2 month or more Having diabetes Having known cardiovascular disease Having known renal disease Hypothyroidism Having any types of cancer

## **Age**

From **18 years** old to **50 years** old

## **Gender**

Female

## **Phase**

3

## **Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## **Sample size**

Target sample size: **80**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 80 specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code (supplement and placebo) at the time of sampling. The following groups of people: participants, research team including principle investigator, data collectors, and

outcome assessors will be blind

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shahid Beheshti medical university

##### **Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1981619573

#### **Approval date**

2022-02-27, 1400/12/08

#### **Ethics committee reference number**

IR.SBMU.RETECH.REC.1400.1133

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Decreased libido

#### **ICD-10 code**

R68.82

#### **ICD-10 code description**

Decreased libido

## **Primary outcomes**

### 1

#### **Description**

sexual function index

#### **Timepoint**

Baseline and at the end of the study

#### **Method of measurement**

sexual function index questionnaire (FSFI)

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### Description

Intervention group: 500 mg Femexite (Ghaem Daro) capsule two times daily for 8 weeks

### Category

Treatment - Other

## 2

### Description

Control group: Placebo contain maltodextrine, (500 mg), Ghaem darou company, two times daily for 8 weeks

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

private clinic

#### Full name of responsible person

Soodeh Razeghi Jahromi

#### Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

#### City

Tehran

#### Province

Tehran

#### Postal code

1981619573

#### Phone

+98 21 2235 7483

#### Email

soodehrazeghi@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Afshin Zarghi

#### Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

#### City

Tehran

#### Province

Tehran

#### Postal code

1981619573

#### Phone

+98 21 2235 7483

#### Email

soodehrazeghi@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

### organization/entity?

Yes

### 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

Soodeh Razghei Jahromi

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

#### Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

#### City

Tehran

#### Province

Tehran

#### Postal code

193954741

#### Phone

+98 21 2235 7483

#### Email

soodehrazeghi@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Soodeh Razghei Jahromi

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

#### Street address

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

#### City

Tehran

#### Province

Tehran

**Postal code**

193954741

**Phone**

+98 21 2235 7483

**Email**

soodehrazeghi@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razghei Jahromi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

193954741

**Phone**

+98 21 2235 7483

**Email**

soodehrazeghi@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**

All data would be available to public

**When the data will become available and for how long**

Starting 6 months after publication

**To whom data/document is available**

To all

**Under which criteria data/document could be used**

No other criteria

**From where data/document is obtainable**

Email to soodehrazeghi@gmail.com

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

Sending email

**Comments**