Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

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

Protocol summary

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

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

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.

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

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.

Main outcome variables
sexual function index using FSFI questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140804018677N15**
Registration date: **2022-04-22, 1401/02/02**
Registration timing: **prospective**

Last update: **2022-04-22, 1401/02/02**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

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

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

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

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