Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of oral traditional Persian medicine product of silk (Bombyx mori L. Cocoon), on sexual dysfunction and Quality of Life in women of reproductive age, compare with placebo. a triple-blind randomized clinical trial

Protocol summary

Study aim

The main goal:Determining the effect of the oral product of traditional Persian medicine product of silk (Bombyx mori L. Cocoon), on sexual dysfunction and Quality of Life in women of reproductive age, compare with placebo.

Design

Clinical trial with control group, parallel groups, triple blind, randomized by epidemiologist, on 74 patients.

Settings and conduct

Patients with sexual dysfunction referred to Health College of Persian Medicine in Qom and medical science clinics in Qom, including Rayhane Infertility Center of Nekoui Hospital, who meet the study entry criteria, are selected by the researcher, then the details of the study will be explained by the researcher, then the questionnaire Demographic characteristics and disease information are adjusted and patients are randomly assigned to one of two treatment groups.

Participants/Inclusion and exclusion criteria

1. Women aged 18-50 years 2. The woman being married and her husband being monogamous 3. FSFI women's sexual function index score<28 in the initial evaluation 4. Patients with BMI less than 30 5. Having informed consent to participate in the study

Intervention groups

Intervention group: The patients will be given traditional Persian medicine products containing silk. Silk syrup is taken three times a day for 3 weeks and 10 cc each time. Control group: patients will be given a placebo product. Placebo syrup is taken 10 cc three times a day for 3 weeks.

Main outcome variables

female sexual function, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221017056213N1**
Registration date: **2022-12-04, 1401/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-04, 1401/09/13**
Update count: **0**

Registration date

2022-12-04, 1401/09/13

Registrant information

Name

fatemeh jahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3776 4075

Email address

fjahani@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of oral traditional Persian medicine product of silk (Bombyx mori L. Cocoon), on sexual dysfunction and Quality of Life in women of reproductive age, compare with placebo. a triple-blind randomized clinical trial

Public title
Evaluation of the effect of oral product of silk (Bombyx mori L. Cocoon), on sexual dysfunction and Quality of Life in women of reproductive age

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 18-50 years The woman being married and her husband being monogamous FSFI women's sexual function index score<28 in the initial evaluation Ability to read, understand and complete the questionnaire People with BMI less than 30 Having informed consent to enter the study

Exclusion criteria:
pregnancy and breastfeeding delaying menstruation for 2 months or more significant clinical findings in physical examination, screening tests or other findings that prevent safe participation in the study, including the presence of any organic, anatomical disease (such as malformation of the anatomy of the external genitalia, spinal cord injuries or related surgery), hormonal in the study group such as diabetes, cerebrovascular disease, liver and kidney function damage, heart disease, hypothyroidism, cancers in history and medical history of psychiatric diseases that are under drug treatment. receiving psychotherapy or other treatments for sexual dysfunction using tobacco, alcohol, drug abuse using any chemical and herbal medicine known to affect libido being participate in another clinical trial study major changes in recent relationships, ongoing or unforeseeable disorder or disturbance that is not related to his sexual dysfunction.

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
- Data and Safety Monitoring Board

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups using the randomized balanced block method with block sizes of 4 and 6. The random sequence is generated by an epidemiologist by running an online program on the website (https://www.sealedenvelope.com). Allocation concealment is also guaranteed due to the use of special codes generated by the website.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, the patient, the researcher (project manager (doctor)) and the statistical consultant will not know about the syrup content and they will be blinded. Only the traditional medicine pharmacist who is responsible for the preparation of Iranian traditional medicine syrup and placebo syrup will know about the content of medicinal syrups. People who meet the inclusion criteria, if they want to participate in the study, after obtaining written informed consent, they will be given the traditional Iranian medicine syrup and placebo, which are in the same packaging and completely similar in terms of appearance, color and aroma. They receive a random face. A special code will be considered for each syrup and will be recorded on the syrup label. Only the pharmacist consultant will know about the drug codes. Medicines will be provided to the doctor and plan administrator and the patient. The code of each syrup specific to each patient will be entered in the patient's file and checklist by the administrator. At the end of the study, the information and checklist form of the patients will be provided to the statistics consultant for statistical analysis, and after the data analysis, the code of syrups will be provided to the administrator and statistics consultant for the final analysis by the pharmaceutical expert.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Qom University of Medical Sciences

Street address
No. 83, Shahid Lotfi Niaser, Shahid Lotfi Niaser, Safashehr St., No. 83

City
Qom

Province
Ghoum

Postal code
3716993456

Approval date

2022-07-04, 1401/04/13

Ethics committee reference number

IR.MUQ.REC.1401.093

Health conditions studied

1

Description of health condition studied

sexual dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

sexual dysfunction

Timepoint

The beginning of the study, the end of the fourth week from the beginning of the intervention, one month after the end of the intervention

Method of measurement

female sexual function index Questionnaire

2

Description

Quality of Life

Timepoint

The beginning and end of the study

Method of measurement

Quality of life questionnaire with 36 questions

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will be given traditional Persian medicine products containing silk. Silk syrup is taken three times a day for 3 weeks and 10 cc each time.

Category

Treatment - Drugs

2

Description

Control group: Patients will be given a placebo product. Placebo syrup is taken 10 cc three times a day for 3 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health College of Persian Medicine in Qom and Medical Sciences Clinics in Qom, including Reihaneh In

Full name of responsible person

fatemeh jahani

Street address

Qom Faculty of Persian Traditional Medicine , next to Alley 44, 15 Khordad Blvd

City

Qom

Province

Ghoum

Postal code

3714848350

Phone

+98 25 3777 3466

Email

fatima.jahani1370@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Dr. Alireza Kohpaei

Street address

No. 8 , Shahid Lotfi Niaser (alley no. 4) , Jihad Danighi Alley , Safashehr St

City

Qom

Province

Ghoum

Postal code

3716993456

Phone

+98 25 3285 2720

Email

research@muq.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

fatemeh jahani

Position

PhD student of traditional medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Faculty of Traditional Persian Medicine of Qom University of Medical Sciences, corner of Alley 44, 15 Khordad Blvd

City

Qom

Province

Ghoum

Postal code

3714848350

Phone

00982537764073-4

Email

fatima.jahani1370@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Dr. fatemeh nojavan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Corner of Alley No.44, Faculty of Persian Traditional Medicine of Qom University of Medical Sciences, 15 Khordad Blvd

City

Qom

Province

Ghoum

Postal code

3714848350

Phone

+98 25 37764073-4

Email

fnojavan@muq.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

fatemeh jahani

Position

PhD student of traditional medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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00982537764073-4

Email

fatima.jahani1370@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data will be sent by researchers upon request. All potential data can be shared after de-identifying individuals.

When the data will become available and for how long

After printing the results of the study

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data will be used only for use in published research

articles and will not be made available to the public in any other way.

From where data/document is obtainable

To receive the desired documents and data, please refer to the Faculty of Traditional Medicine of Qom University of Medical Sciences.

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

The data will be accessible from the time of announcing the request to the responsible person and proving the scientific documents of the applicant that they are working researchers at the university, as well as reviewing the relevant study and research.

Comments