Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Effects of oral Shilajit tablet on sexual function and sexual quality of life among married women of reproductive age: A triple blind; randomized; controlled; clinical trial study

Protocol summary

Study aim

Determining the effect of oral Shilajit pill on performance and sexual quality of married women of reproductive age

Design

The clinical trial with the control group will be divided into two groups of intervention and control with parallel groups, three-way blind, randomized, phase 1 per 100 people and for randomization by block randomization method

Settings and conduct

.In the first stage, the researcher, after obtaining the necessary permits from the Vice Chancellor for Research, Tarbiat Modares School of Medical Sciences, University Ethics Committee, registers the research project in the IRCT system, by referring to health centers and health centers affiliated to Qom University of Medical Sciences. Research will be conducted to collect samples.

Participants/Inclusion and exclusion criteria

Women aged 45-18 yearsWomen aged 45-18 years Being Iranian and living in Tehran Be literate Husband monogamy and living with the spouse now and during the study Having sex in the last two months No underlying disease Do not have mental illness Couples not addicted to drugs and alcohol Do not take drugs that affect sexual function Have no history of being a rape victim Sensitivity to shilajit Do not be pregnant or breastfeeding Not wanting to stay in the study Do not take shilajit pills regularly Active wound or lesion in the genital area

Intervention groups

The intervention group is the group that takes the pill and the control group is the group that will take the placebo. Necessary training on taking medication and placebo will be given to both groups face to face. Shilajit tablets with a dose of 200 mg will be taken twice a day for 60 days, and in the third month only the shelf life and effectiveness of the drug will be evaluated.

Main outcome variables

Evaluation of women's sexual function with the FSFI questionnaire; Evaluation of women's sexual quality of life with SQOL_F questionnaire

General information

Reason for update

Sample size changed as follows: Considering the mean scores of one month after the intervention in the pilot group, the mean FSFI of the control group was 24.65 and the mean of the intervention group was 26.93. Including SD: 1.69, the first error of 0.05 and the second error of 80%, the sample size was calculated for each group of 20 people, which with the loss of 20%, 24 people were considered for each group.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200617047808N1**
Registration date: **2020-11-26, 1399/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-05, 1400/06/14**
Update count: **1**

Registration date

2020-11-26, 1399/09/06

Registrant information

Name

sediqa Mosavi

Name of organization / entity

The university of tarbiat Modares

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-05, 1399/08/15
Expected recruitment end date
2021-06-30, 1400/04/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of oral Shilajit tablet on sexual function and sexual quality of life among married women of reproductive age: A triple blind; randomized; controlled; clinical trial study

Public title
Effect of oral shilajit pill on female sexual function and quality of life
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 45-18 years Iranian and living in Tehran Literacy in Persian Husband monogamy and living with the spouse now and during the study Having sex in the last two months(According to the research unit) No known underlying disease (diabetes, hypertension, asthma, heart disease, thyroid, pelvic visceral prolapse, tumor, other medical diseases, hyperlipidemia ...) Do not have mental illness(According to the research unit or file) Couples not addicted to drugs and alcohol(According to the research unit or file) Do not use drugs that affect sexual function in the questionnaire (according to the research unit or file) Have not had a stressful accident in the past month (according to the research unit) Do not have a urinary tract infection (according to a recent research unit or test) No vaginitis, cervicitis, pelvic genital pain disorders, active wound or genital lesion that interferes with sexual intercourse (penetration) (according to the examination and according to the statement of the research unit or file) Has no history of being a rape victim (according to the research unit) Has no history of infertility (according to the research unit) No history of pelvic surgery (colpuraphy or correction according to the research unit or file) Not sensitive to shellac or its compounds (according to the research unit) Not pregnant or breastfeeding (according to the research unit)
Exclusion criteria:
Not wanting to stay in the study Do not take Shilajet tablets regularly (use less than 80% of cases) Sensitivity to Shilajet pills or side effects during the study (according to the research unit) Creating an active wound or lesion in the genital area that interferes with sexual intercourse (penetration) during the intervention (according to the research unit) Consumption of drugs affecting sexual function during the intervention (according to the research unit) Experience of a stressful incident during the intervention (according to the research unit) Urinary tract infection, vaginitis, cervicitis, pelvic genital pain disorders, sexual abuse during the intervention (according to the research unit) Pregnancy during the intervention (according to the research unit or a positive pregnancy test)
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
1
Groups that have been masked

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

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Research units of married women of childbearing age who are unlikely and easy to enter the study from the research community according to the entry and exit criteria of research units. In the first stage, the research units will be divided into two groups of intervention and control based on the inclusion and exit criteria of screening and then randomly block using quadruple random blocks. This method strikes a balance in the allocated samples. In this way, we first design blocks of 4 types of available probabilities, so that in each block there are two people from the intervention group and two people from the control group. The number of probabilities in this case will be equal to 6.AABB(1)-BBAA(2)-ABBA(3)- BAAB(4)- BABA(5)- ABAB(6)Then the list of available modes is prepared and numbered by the tutor and we sort the blocks based on random numbers from 1 to 6. Matte envelopes in the package will be used in numbered order to hide the allocation. The researcher randomly picks up the envelopes and then enters the research units into the sampling system in order.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study will be a phase 1 three-blind clinical trial with placebo control group. The method of blinding is that the researcher and the research units and statistical analysts will also be unaware of the type of drug used and the placebo drug will be prepared by the pharmacist in the same form and with a special code and will be provided to the research units. Participants and researchers will be unaware of the drug codes and only the pharmacist will determine the drug code and after collecting and completing the study, these codes will be decoded.
Placebo
Used
Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
tarbiat modares university

Street address
No.7. Jalal Al Ahmad Street, Tehran

City
Tehran

Province
Tehran

Postal code
14115-111

Approval date
2020-10-27, 1399/08/06

Ethics committee reference number
ir.modares.rec.1399.106

Health conditions studied

1

Description of health condition studied
Performance and quality of women's sexual life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Sexual function

Timepoint
3 times at intervals of 1 month

Method of measurement
Female Sexual Function Index (FSFI Questionnaire)

2

Description
sexual quality of life-Female

Timepoint
3 times at intervals of 1 month

Method of measurement
sexual quality of life-Female (SQOL-F) Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group is the group that takes 200 mg shilajit tablets.

Category
Treatment - Drugs

2

Description
Control group: The control group is the group that will take the placebo

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Khark Traditional Medicine Health Center

Full name of responsible person
Maliha Tabraei

Street address
No. 10, corner of Saeb Alley, Khark St., beginning of Hafez Bridge, Enghelab St., Tehran

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2

Recruitment center

Name of recruitment center
Ahmadiyya Traditional Medicine Health Center

Full name of responsible person
Maliha Tabraei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azam rahmani

Street address

Tehran, Shahid Chamran Highway, Yemen St., Shahid Shahriari Square, Daneshjoo Blvd.

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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

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

tarbiat modares university

Full name of responsible person

shadab shahali

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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shadab.shahali@modares.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

دانشگاه علوم پزشکی تهران- مرکز تحقیقات مراقبت های پرستاری و مامایی

Full name of responsible person

azam rahmani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data, including information about the main outcome, can be shared.

When the data will become available and for how long

Access period from 2021

To whom data/document is available

The data will only be available to field researchers

Under which criteria data/document could be used

For further research, researchers can send a written request to the responsible author

From where data/document is obtainable

Corresponding Author, Tarbiat Modares University, Faculty of Medical Sciences, Department of Midwifery and Reproductive Health

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

After a written request from the responsible author, the request will be sent to the research unit of Tarbiat Modares University and if the rules are complied with, the analyzed data will be provided to the researchers.

Comments