# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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**

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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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http://spm.tums.ac.ir/content/3316/%D8%B3%D9%84%D8%A7%D9%85%D8%AA%DA%A9%D8%AF%D9%87-%D9%87%D8%A7.html

### 2

**Recruitment center**

**Name of recruitment center**
Ahmadiyya Traditional Medicine Health Center

**Full name of responsible person**
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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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## Person responsible for scientific inquiries

**Contact**

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

**Full name of responsible person**

azam rahmani

**Position**

Assistant Professor

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## Person responsible for updating data

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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**