

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Topical effect an oil, derived from black seed, on women's sexual function: A pilot clinical trial

#### Protocol summary

##### Study aim

Determining the effect of black seed-extracted oil on the sexual function of women

##### Design

The study consists of one group and the intervention is the same for all. The study design is applied phase-two research in the field of clinical science. In addition, the sample size is 40 people.

##### Settings and conduct

The objective of this intervention is to investigate the effect of a combinatory medication on the basis of black seed on the sexual function of women. Location of research: Ahmadi Health Center in Tehran University of Medical Sciences. examination session.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Married women with a stable life with their spouse, having the least reading and writing education skills, having intercourse of three times or more during the study. Exclusion criteria: Diagnosis of chronic physical, psychological and behavioral illnesses, being multi-partner, using hormonal drugs and drugs affecting sexual function, pregnancy, lactation, and menopause.

##### Intervention groups

40 women with an age range of 18- 35 years with sexual dysfunction are selected for the study. Medication it is used locally every night before bedtime, and once before intercourse in the area of the sex organs, inguinal area, low back, and soles. The duration of the intervention period is 14 days.

##### Main outcome variables

Score of sexual function; sexual desire or interest; satisfied in sexual relationship; sexual arousal; maintain vaginal lubrication until completion of intercourse based on FSFI questionnaire.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190527043729N1**

Registration date: **2019-07-28, 1398/05/06**

Registration timing: **retrospective**

Last update: **2019-07-28, 1398/05/06**

Update count: **0**

##### Registration date

2019-07-28, 1398/05/06

##### Registrant information

##### Name

leila ghanbaryan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 5283 2978

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l-ghanbaryan@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-11, 1397/12/20

##### Expected recruitment end date

2019-07-22, 1398/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Topical effect an oil, derived from black seed, on women's sexual function: A pilot clinical trial

**Public title**

effect of a combinatory medication on the basis of black seed on the sexual function of women.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Married women with a stable life with their spouse having the least reading and writing education skills. having intercourse of three times or more during the study.

**Exclusion criteria:**

Diagnosis of chronic physical, psychological and behavioral illnesses. being multi-partner using hormonal drugs and drugs affecting sexual function. pregnancy, lactation, and menopause.

**Age**

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

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

**Street address**

Alborz University of Medical Sciences, Official Town, North Taleghani Blvd.

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KARAJ

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**Postal code**

3149779453

**Approval date**

2019-03-09, 1397/12/18

**Ethics committee reference number**

IR.ABZUMS.REC.1398.003

**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

**2****Description of health condition studied**

Lack or loss of sexual desire

**ICD-10 code**

F52.0

**ICD-10 code description**

Hypoactive sexual desire disorder

**3****Description of health condition studied**

Lack or loss of sexual enjoyment

**ICD-10 code**

F52.1

**ICD-10 code description**

Sexual aversion disorder

**4****Description of health condition studied**

Lack or loss of female sexual arousal disorder

**ICD-10 code**

F52.22

**ICD-10 code description**

Female sexual arousal disorder

**Primary outcomes****1****Description**

Score of sexual function based on Female sexual function index questionnaire

**Timepoint**

Measurement of sexual function at the time of entering the study (before intervention), on the seventh day, and on the 14th day, After starting the oil based on black seed

**Method of measurement**

Female sexual function index questionnaire

**2****Description**

Score of sexual desire or interest based on Female sexual function index questionnaire

**Timepoint**

Measurement of sexual function at the time of entering the study (before intervention), on the seventh day, and on the 14th day, After starting the oil based on black seed.

**Method of measurement**

Female sexual function index questionnaire

**3**

**Description**

Score of satisfied in sexual relationship based on Female sexual function index questionnaire

**Timepoint**

Measurement of sexual function at the time of entering the study (before intervention), on the seventh day, and on the 14th day, After starting the oil based on black seed.

**Method of measurement**

Female sexual function index questionnaire

**4**

**Description**

Score of sexual arousal based on Female sexual function index questionnaire

**Timepoint**

Measurement of sexual function at the time of entering the study (before intervention), on the seventh day, and on the 14th day, After starting the oil based on black seed.

**Method of measurement**

Female sexual function index questionnaire

**5**

**Description**

Score of maintain vaginal lubrication until completion of intercourse based on Female sexual function index questionnaire

**Timepoint**

Measurement of sexual function at the time of entering the study (before intervention), on the seventh day, and on the 14th day, After starting the oil based on black seed.

**Method of measurement**

Female sexual function index questionnaire

**Secondary outcomes**

**1**

**Description**

Skin itching

**Timepoint**

On the seventh day, and on the 14th day, After starting the oil based on black seed

**Method of measurement**

Observation

**2**

**Description**

Skin irritation

**Timepoint**

On the seventh day, and on the 14th day, After starting the oil based on black seed

**Method of measurement**

Observation

**Intervention groups**

**1**

**Description**

Intervention group: The study consists of one group and the intervention is the same for all. 40 women with an age range of 18- 35 years with sexual dysfunction are selected for the study, according to inclusion and non-inclusion criteria. The duration of the intervention period is 14 days. In order to evaluate the patients, the female sexual function index (FSFI) is completed during each examination session. In the first and second stage, they will receive medication. The name of the medicinal product: olibanum oil. Product description: a topical product based on black seed oil containing olibanum and olive oil. Company Name: Amir herbal medicine. Medication instructions for use: The medication is used locally every night before bedtime, and once before intercourse in the area of the sex organs, inguinal area, low back, and soles. Time of drug use: from the 14th day of the menstrual bleeding cycle, the nights before bedtime for 14 days and, once before any Sexual Intercourse.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ahmadih Iranian Medicine Health Center in Tehran University of Medical Sciences.

**Full name of responsible person**

Tabarraei Malihe

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No. 27, Tbriz Line, North Sarparast Ave., Taleghani Ave.

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**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Noori Sepehr Mohammad

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Assistant Professor of Research and  
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dr.noorisepehr@abzums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Karaj 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Leila Ghanbaryan

**Position**

PHD Student

**Latest degree**

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**Other areas of specialty/work**

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### 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 potential data can be shared after being unidentified.  
**When the data will become available and for how long**  
The start of the access period will be 6 months after the publication of the results.  
**To whom data/document is available**

Data will only be available to researchers working in academic and academic institutions.  
**Under which criteria data/document could be used**  
Data will only be available for use in research articles and will not be publicly available in any other way.  
**From where data/document is obtainable**  
Please refer to the Faculty of Traditional Medicine of Tehran University of Medical Sciences for documentation and data. Dr. Meysam Shirzad, Assistant Professor, Department of Iranian Medicine. address: no 27., Sarparast Ave., taleghni Ave. Contact number: 02188974535 Electric mail: shirzadmd@gmail.com  
**What processes are involved for a request to access data/document**  
The data will be available from the time the application is filed to the person responsible for the scientific evidence of the person requesting that the researcher working in the university and the study of the relevant study.  
**Comments**