Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 pepole.

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: Ahmadieh 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)

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+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 Scienes
Street address
Alborz University of Medical Sciences, Official Town, North Taleghani Blvd.
City
KARAJ
Province
Alborz
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

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

Full name of responsible person

Tabarrai Malihe

Street address

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

Street address
Assistant Professor of Research and Technology,Alborz University of Medical Sciences, Saffarian Line, 45 Yards Golshahr

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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
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
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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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