Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The effect of rose oil essence on the sexual dysfunction of women

Protocol summary

Summary

The purpose of this study is evaluate the efficacy of Rosa damascenes extracts in the treatment of sexual dysfunction in women. This is a triple-blind clinical trial. Research Environment is traditional medicine clinics and centers affiliated to Tehran University of Medical Sciences. Patients with diagnoses of sexual dysfunction, as well as the other criteria will be entered into the study. 80 married women referred to this centers were selected and randomly divided into two groups. The intervention group receive Soft capsule twice a day containing 15 mg of extract (standardized on the basis of at least 5/7 mg per capsule, soft citronellol) for 8 weeks. The control group received placebo. Placebo with similar appearance and only sesame oil or soybean oil would be, So that samples are unaware of the contents of the capsules. Then at the beginning of the study, four and eight week of the study, libido,sexual arousallevels, orgasmic disorders, sexual pain disorders and sexual satisfaction were examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051333951N1**
Registration date: **2017-06-11, 1396/03/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

mohadeseh motaharinezhad

Name of organization / entity

school of midwifery and nursing, Tehran university of medical science

Country

Iran (Islamic Republic of)

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+98 21 8879 4301

Email address

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Recruitment status

Recruitment complete

Funding source

Barij Essence Pharmaceutical companies

Expected recruitment start date

2016-12-20, 1395/09/30

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rose oil essence on the sexual dysfunction of women

Public title

The effect of rose oil essence on the sexual dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included all the married women have a stable life with wife, At least read and write, Not during pregnancy and lactation and menopause, Without having any chronic disease(self reported), Absence of mental illness known -Psychic(self reported), Non-hormonal drugs and drugs that affect sexual desire and performance(Such as antidepressants, aspirin and anticoagulants), According to the questionnaire, the Female Sexual Function Index (FSFI) questionnaire impaired sexual function, according to Beck (BDI) is a non-depressive illness, Is not a multi-partner, The lack of

adverse events in at least 6 months, Lack of substance abuse and alcohol in a person and The absence of a partner's sexual dysfunction (premature ejaculation, erectile dysfunction) self-reported is. Exclusion criteria included Not wanting to continue to participate in research, Lack of sex during the study, Drugs only affect sexual function during the study, Diagnosis of chronic disease and mental - mental in person during the period of study(self-reported), No drug or placebo for a week or more and Disasters like the loss of a spouse or close relative during the study period.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
tehran university of medical science

Street address
Ghods St., Keshavarz Blvd.

City
tehran

Postal code

Approval date
2016-08-22, 1395/06/01

Ethics committee reference number
IR.TUMS.FNM.REC.1395.483

Health conditions studied

1

Description of health condition studied
Sexual Dysfunction

ICD-10 code
F52

ICD-10 code description
Sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description
sexual function

Timepoint
Before the intervention, 4 weeks after starting treatment and after the treatment at week 8

Method of measurement
FSFI Standardized questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Rosafeel Barij, soft capsule containing 15 mg of Rose essential oil (standard on the basis of at least 5/7 mg per capsule citronellol) twice a day for 8 weeks.

Category
Treatment - Drugs

2

Description
Placebo, soft capsules, containing Sesame oil or soy, twice a day for 8 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahmadiyya clinic

Full name of responsible person
Dr Malihe tabaraei

Street address
Palestine Square North sarparast Street No. 27

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Barij Essence Pharmaceutical companies

Full name of responsible person

Leyla taghizadeh

Street address

Kashan

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Barij Essence Pharmaceutical companies

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

school of midwifery and nursing, Tehran university of medical science

Full name of responsible person

Mohadeseh motaharinezhad

Position

Post graduate student of midwifry

Other areas of specialty/work

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PhD in Reproductive Health

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty