

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of date palm pollen on sexual disorder in menopausal women affiliated by Comprehensive Health Services Centers in Rafsanjan ,2019.

Protocol summary

Study aim

Determination the effect of palm pollen on sexual disorder of women covered by Rafsanjan Comprehensive Health Care Centers year 1398

Design

A randomized controlled clinical trial with parallel groups, three blinded, randomized

Settings and conduct

The researcher, after approving the project in the Research Council of Rafsanjan University of Medical Sciences and obtaining the code of ethics and obtaining the necessary authorization to conduct research from the university, will refer to the midwifery units. Thus postmenopausal women are screened for entry requirements and if eligible, explaining the purpose of the study, they are invited to participate in the project and they will enter the study with written consent. Individuals will be assigned to the intervention and control groups randomly and it will be by lottery. The intervention group will be given 30 palm pollen capsules and the control group the same number of placebo capsules for one month, one capsule daily. The participants, the researcher, the data collector, and the statistical consultant are unaware of the type of medicine and the study will be three-blind.

Participants/Inclusion and exclusion criteria

Inclusion in the study: Age between 50 and 65 years At least 12 months or more since the last menstrual period
Exclusion from the study: breast and uterine cancers, abnormal vaginal bleeding, depression or known mental disorders use of progestin hormone pills, contraceptive pills, agonists and gonadotropin releasing hormone antagonists, taking other herbal remedies regularly, liver, kidney and thyroid diseases

Intervention groups

The intervention group received palm pollen capsules for 4 weeks at a daily dose of 300 mg and the control group received placebo capsules similar to the intervention capsules filled with starch for 4 weeks.

Main outcome variables

Status of sexual disorders with the use of date pollen capsules

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160308026971N10**

Registration date: **2020-12-06, 1399/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-06, 1399/09/16**

Update count: **0**

Registration date

2020-12-06, 1399/09/16

Registrant information

Name

Marzeyeh Loripoor

Name of organization / entity

Rafsanjan University Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

m.loripoor@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of date palm pollen on sexual disorder in menopausal women affiliated by Comprehensive Health Services Centers in Rafsanjan ,2019.

Public title

Investigating the effect of date palm pollen on sexual disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 65-50 years At least 12 months or more since the last menstrual period Informed and free consent to participate in the study

Exclusion criteria:

breast and uterine cancers, abnormal vaginal bleeding, depression or known mental disorders use of progestin hormone pills, contraceptive pills, agonists and antagonists gonadotropin releasing hormone Use of any herbal remedies Known diseases of the liver, kidney and thyroid Taking any hormone or non-hormonal drug

Age

From **50 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation to the intervention and control groups is random and will be by lottery. Put 55 sheets of code 1 and 55 of code 2 , in a container and stir. We ask each participant to remove one of the sheets from the container and randomly fall into one of the capsule consumption groups with code 1 or code 2.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Drug maker packs palm pollen and placebo capsules with codes 1 and 2 and is provided to postmenopausal women by a researcher or data collector.The questionnaires will be marked with codes 1 and 2, then the completed questionnaires are submitted to the statistical consultant for analysis.thus, the women participating in the project, the researcher, the data collector, and the statistical advisor of the type of drug will be unaware and the study will be three-blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

National Committee on Ethics in Biomedical Research

Street address

Central Organization of Rafsanjan University of Medical Sciences and Health Services, Deputy of research and technology, Imam Ali Boulevard

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2020-07-25, 1399/05/04

Ethics committee reference number

IR.RUMS.REC.1399.097

Health conditions studied**1****Description of health condition studied**

sexual disorder

ICD-10 code

F66

ICD-10 code description

Other sexual disorders

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

sexual disorder

Timepoint

Before intervention, End of intervention, 4 weeks after intervention

Method of measurement

Based on FSFI questionnaire

Secondary outcomes**1****Description**

Sexual dysfunction score

Timepoint

Before intervention, End of intervention, 4 weeks after intervention

Method of measurement

Based on FSFI questionnaire

Intervention groups

1

Description

Intervention group: Use 30 capsules of palm pollen at a dose of 300 mg daily for one month

Category

Treatment - Drugs

2

Description

Control group: Take 30 placebo capsules at a dose of 300 mg daily for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Service Centers

Full name of responsible person

Fatemeh Esmaeili

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Shohada Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

marzeyeh loripoor

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Marzeyeh Loripoor

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Position

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Latest degree

Ph.D.

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Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available