

# 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

+98 34 3428 4950

##### 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

**Street address**

Shohada Ave.

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info@rums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

marzeyeh loripoor

**Street address**

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

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alishamsy@gmail.com

**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

**Street address**

Faculty of Nursing and Midwifery, Nursing street

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**Postal code**

7718796755

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**Email**

marzeyehloripoor@yahoo.com

**Person responsible for scientific 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.

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

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**Phone**

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**Email**

marzeyehloripoor@yahoo.com

**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