

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect Of Date Palm Pollen Capsul On Sexual Function In Menopausal Woman: A randomized controlled clinical trial.

Protocol summary

Summary

The aim of this Double blind randomized controlled trial is to determine the effect of Date Palm Pollen Capsule on sexual function in postmenopausal women. We will recruit 60 menopausal aged 50-60 years women from public health centers in Mashhad (2016), Iran. Inclusion criteria: Iranian women, Fifth grade of Elementary School, age 40-65 years for a research unit or her Spouse, Women with natural menopause, Married women and having sex at least once a month, desire to participate in the research. Exclusion criteria: Having any sexual dysfunction before menopause, Known medical conditions affecting sexual function in research unit or her Spouse, Research Unit or her Spouse have Consumption Drugs affecting sexual performance during the past three months, Experience some unpleasant or stressful life events in the past 6 months by the Research Unit or her Spouse, Research Unit have to be sensitive to pollen and medicinal plants, treated with hormonal drug, Research Unit or her Spouse addiction to drugs or alcohol. After getting written informed consent, participants will complete a self-administered questionnaire about demographic and reproductive history and also questions about Female Sexual Function Index (FSFI).The participants will be randomly divided in intervention and control groups (30 women in each group).The intervention group will receive Date Palm Pollen, 300 mg capsule, once daily for 5 week and the control group will receive placebo capsule, at the same dose as the intervention group. The participants will complete FSFI post -test questionnaires 5 weeks after intervention. The mean of difference in sexual function scores are compared among two groups. In this study we keep blinding for participants and researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070928853N1**

Registration date: **2016-12-09, 1395/09/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-09, 1395/09/19

Registrant information

Name

Somaye Sadeghi Goghari

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2081

Email address

sadeghis922@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2016-08-20, 1395/05/30

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Date Palm Pollen Capsul On Sexual Function In Menopausal Woman: A randomized controlled

clinical trial.

Public title

The Effect Of Date Palm Pollen Capsul On Sexual Function In Menopausal Woman

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Iranian women, Fifth grade of Elementary School, age 40-65 years for a research unit or her Spouse, Women with natural menopause, Married women and having sex at least once a month, desire to participate in the research. Exclusion criteria: Having any sexual dysfunction before menopause, Known medical conditions affecting sexual function in research unit or her Spouse, Research Unit or her Spouse have Consumption Drugs affecting sexual performance during the past three months, Experience some unpleasant or stressful life events in the past 6 months by the Research Unit or her Spouse, Research Unit have to be sensitive to pollen and medicinal plants, treated with hormonal drug, Research Unit or her Spouse addiction to drugs or alcohol.

Age

From **40 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2016-05-21, 1395/03/01

Ethics committee reference number

IR.MUMS.REC.1395.183

Health conditions studied

1

Description of health condition studied

Sexual Function In Menopausal Woman

ICD-10 code

F52.9

ICD-10 code description

Unspecified sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description

Sexual Function

Timepoint

Before intervention and 35 day after taking the capsules.

Method of measurement

Female Sexual Function Index(FSFI)

Secondary outcomes

1

Description

Sexual Function

Timepoint

Before intervention and 35 day after taking the capsules.

Method of measurement

Femal Sex Function Index

Intervention groups

1

Description

Control group: be taken daily 300 mg placebo capsules for 35 days.

Category

Treatment - Drugs

2

Description

Interventional group: be taken daily 300 mg oral Date Palm Pollen capsules for 35 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashemi Nejad Health and Treatment Center

Full name of responsible person

Somaye Sadeghi Goghari

Street address

Faculty of Nursing and Midwifery, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of
Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
Street, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of
Medical Sciences

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

Faculty of Nursing and Midwifery, Mashhad

Full name of responsible person

Somaye Sadeghi Goghari

Position

Instructor of Midwifery

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Crossroads Doktora,

street Ebn Sina,Mashhad

City

Mashhad

Postal code

Phone

+98 917 575 0127

Fax

Email

Sadeghis922@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Mashhad

Full name of responsible person

Sedighe Yosef Zade

Position

Instructor of Midwifery

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Crossroads Doktora,
street Ebn Sina,Mashhad

City

Mashhad

Postal code

Phone

+98 915 320 2371

Fax

Email

Yosefzadehs@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Mashhad

Full name of responsible person

Somaye Sadeghi Goghari

Position

Masters Student

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Crossroads Doktora,
street Ebn Sina,Mashhad

City

Mashhad

Postal code

Phone

00

Fax

Email

Sadeghis922@mums.ac.ir

Web page address

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