Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of date palm pollen on menopausal symptoms in women affiliated by Comprehensive Health Services Centers in Rafsanjan ,2019

Protocol summary

Study aim

Determination the effect of palm pollen on menopausal symptoms 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

The status of menopausal symptoms with palm pollen capsules

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160308026971N6**
Registration date: **2020-01-03, 1398/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-03, 1398/10/13**
Update count: **0**

Registration date

2020-01-03, 1398/10/13

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

Investigating the effect of date palm pollen on menopausal symptoms in women affiliated by Comprehensive Health Services Centers in Rafsanjan ,2019

Public title

Investigating the effect of date palm pollen on menopausal symptoms

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 any herbal remedies Abnormal vaginal bleeding Known diseases of the liver, kidney and thyroid Taking any hormone or non-hormonal drug use of progestin hormone pills, contraceptive pills, agonists and antagonists gonadotropin releasing hormone

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

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

Imam Ali Boulevard, Central Organization of Rafsanjan University of Medical Sciences, Vice Chancellor for Research,

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2019-11-11, 1398/08/20

Ethics committee reference number

IR.RUMS.REC.1398.142

Health conditions studied

1

Description of health condition studied

Symptoms of Menopause

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Symptoms of Menopause

Timepoint

Before intervention, End of intervention, 4 weeks after intervention

Method of measurement

Based on MRS questionnaire

Secondary outcomes

empty

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
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alishamsy@gmail.com
Web page address
http://vcrt.rums.ac.ir
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
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Marzeyeh Loripoor
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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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