

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Phoenix Dactylifera Spathe vaginal gel on sexual function and Vaginal Atrophy in Menopausal women

Protocol summary

Study aim

Determining the effect of Phoenix Dactylifera Spathe vaginal gel on sexual function and vaginal atrophy in postmenopausal women

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 110 patients, a computer random number table is used for randomization and through blocking of 6 and 9.

Settings and conduct

Research in health centers of Shushtar city, which is first identified by screening patients and then randomly entered into intervention and control groups. using similar and opaque packets containing drugs Which are numbered from 1 based on the allocation sequence.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Existence of symptoms of vaginal atrophy; Sexual function score less than 26/55 Exclusion criteria: Use of psychiatric drugs, Fluoxetine, Vitamin E, Propranolol and other chemical or herbal medicines that affect the symptoms of menopause

Intervention groups

Individuals in the intervention group are given 5% vaginal gel of Phoenix Dactylifera Spathe plant once a day, and the control group is given a vaginal gel placebo (containing gel and preservative) that looks similar to Phoenix Dactylifera Spathe extract gel. It is given once a day for 1 month.

Main outcome variables

Sexual function; Vaginal atrophy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210517051331N1**

Registration date: **2021-06-07, 1400/03/17**

Registration timing: **prospective**

Last update: **2021-06-07, 1400/03/17**

Update count: **0**

Registration date

2021-06-07, 1400/03/17

Registrant information

Name

Rana Rezaei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Phoenix Dactylifera Spathe vaginal gel on sexual function and Vaginal Atrophy in Menopausal women

Public title

The effect of Phoenix Dactylifera Spathe vaginal gel on sexual function and Vaginal Atrophy in Menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being married Be literate No medical condition of the woman or her husband (according to Ms. Menopause) Age range under 65 years More than a year has passed since the last menstrual period Having sex for the past month Have sex at least once a month Existence of symptoms of vaginal atrophy Sexual function score less than 26/55

Exclusion criteria:

Any physical or motor disability Training on sexual issues in the last 4 weeks Use of psychiatric drugs, Fluoxetine, Vitamin E, Propranolol and other chemical or herbal medicines that affect menopausal symptoms Smoking and alcohol or drug use

Age

To 65 years old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: 110

Randomization (investigator's opinion)

Randomized

Randomization description

The grouping of the subjects in each of the intervention and control groups (55 people in each group) is done randomly (random allocation) using a computer random number table and through blocks of 6 and 9 and by a statistician.

Blinding (investigator's opinion)

Double blinded

Blinding description

To conceal allocation, similar and opaque packets are used containing drugs Which are numbered from 1 based on the allocation sequence.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Unit 5, Parand Apartment, Shahid Afzalan Street, Komite Sokht

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Province

Khouzestan

Postal code

6451854313

Approval date

2021-05-09, 1400/02/19

Ethics committee reference number

IR.AJUMS.REC.1400.093

Health conditions studied

1

Description of health condition studied

Sexual function in menopause; Vaginal atrophy in menopause

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

Vaginal atrophy- Maturity index of vaginal mucosa cells

Timepoint

Before the study and 30 days after taking Phoenix Dactylifera Spathe vaginal gel

Method of measurement

To examine the maturity index of vaginal mucosal cells, using a sterile cotton swab, a sample of vaginal secretions and posterior fornix is taken and spread on the slide. The slide is then fixed with a fixator and placed in envelopes on which the patient's profile is written. Then, the slides prepared from the patients are sent to the pathology laboratory of Ahwaz Jundishapur University of Medical Sciences and the samples are examined for vaginal atrophy.

2

Description

Mental symptoms of vaginal atrophy

Timepoint

Before the study and 30 days after taking Phoenix Dactylifera Spathe vaginal gel

Method of measurement

Mental symptoms of vaginal atrophy will be assessed according to a 4-point self-assessment scale of a combined score including: burning, itching, vaginal dryness and dyspareunia, so that the severity of each symptom is determined by the patient and then a score according to criterion 4 A degree (0 = absence, 1 = mild = 2 moderate and 3 = severe) was given to them by the researcher and by adding the numbers related to each of

the symptoms, the combined score will be calculated.

Placebo

3

Description

Vaginal PH

Timepoint

Before the study and 30 days after taking Phoenix
Dactylifera Spathe vaginal gel

Method of measurement

During vaginal examination with a speculum, a paper strip of pH meter is contacted to the vaginal wall with a pair of pliers and held for one minute.

4

Description

Clinical signs of Vaginal atrophy

Timepoint

Before the study and 30 days after taking Phoenix
Dactylifera Spathe vaginal gel

Method of measurement

Clinical signs of atrophy are assessed by completing a descriptive evaluation table of vaginal mucosa, and if there are at least 2 symptoms of the table (vaginal folds, color, petechiae, elasticity and vaginal dryness) vaginal atrophy is diagnosed.

5

Description

Sexual Function

Timepoint

Before the study and 30 days after taking Phoenix
Dactylifera Spathe vaginal gel

Method of measurement

Using a questionnaire FSFI

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Phoenix Dactylifera Spathe vaginal gel 5% of Phoenix Dactylifera Spathe plant once a day for one month. Phoenix Dactylifera Spathe vaginal gel is made in the Faculty of Pharmacy of Ahwaz Jundishapur University.

Category

Treatment - Drugs

2

Description

Control group: placebo vaginal gel containing gel and preservative will be used once a day for a month. Placebo vaginal gel is made in the Faculty of Pharmacy of Ahwaz Jundishapur University.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 1 of Shoushtar city

Full name of responsible person

Mohamad Ali Malek Nesa

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2

Recruitment center

Name of recruitment center

Health Center No. 2 of Shoushtar city

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3

Recruitment center

Name of recruitment center

Health Center No. 3 of Shoushtar city

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4

Recruitment center

Name of recruitment center

Health Center No. 4 of Shoushtar city

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5

Recruitment center

Name of recruitment center

Health Center No. 5 of Shoushtar city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Rana Rezaei

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

5, Parand Building, Shahid Afzalan street, Komite
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Shoushtar

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