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
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
- City
  Shoushtar
- Province
  Khuzestan
- 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 Ahvaz 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.

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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Taleghani Street

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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

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Name of recruitment center
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5

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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
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
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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