

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparison of the effect of date pollen and placebo on improving of sexual function in sexually active women 25-45 years old: a double blind clinical trial

#### Protocol summary

##### Study aim

The effect of Date pollen pills to improve female sexual function

##### Design

The present study is a double-blind clinical trial on 50 sexually active women 25-45 years. The data collection method will be convenience sampling, then the blocking method will be used for random allocation of the intervention and control groups. In this way, 6 status of the 4-block were inserted into the paper sheets, then the papers were randomly removed (with replacement) and the random arranged was determined until the desired sample size was reached

##### Settings and conduct

All women ages 25 to 45 years old who use IUD for contraceptive refer to Health Care Centers (No. 1,2 and 3) in Khalkhal City. Samples and clinical caregivers will be blind.

##### Participants/Inclusion and exclusion criteria

Giving Informed consent, having a husband, having an IUD at least six months in advance, ages 25-45 years, Not having abortions in the past six months, Having no infant, Not having cognitive and systemic psychological disorders affecting sexual function, having at least reading literacy and writing, not using drugs that affect sexual function, insensitivity to herbs and pollen, no smoking, alcohol or drugs

##### Intervention groups

Intervention group: Daily use of tablets containing 300 mg of palm pollen for 35 days Control group: Daily use of placebo for 35 days

##### Main outcome variables

Sexual Function Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190622043970N1**

Registration date: **2020-01-02, 1398/10/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-02, 1398/10/12**

Update count: **0**

##### Registration date

2020-01-02, 1398/10/12

##### Registrant information

##### Name

roghayeh salmani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3243 3017

##### Email address

r.salmani@khalums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-12-22, 1398/10/01

##### Expected recruitment end date

2020-02-20, 1398/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of date pollen and placebo on

improving of sexual function in sexually active women  
25-45 years old: a double blind clinical trial

### Public title

The effect of date pollen on sexual function

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Conscious consent, Having a husband having an IUD at least six months in advance ages 25-45 years Not having abortions in the past six months Having no infant Not having cognitive and systemic psychological disorders affecting sexual function having at least reading literacy and writing not using drugs that affect sexual function insensitivity to herbs and pollen no smoking, alcohol or drugs

#### Exclusion criteria:

Unwillingness to continue research being away from husband for various reasons and having another spouse having depression breast feeding abortion or children death during the past six months pregnancy allergy to dates

### Age

From **25 years** old to **45 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

- Participant
- Care provider

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The data collection method will be convenience sampling, then the blocking method will be used for random allocation of the intervention and control groups. 6 status of the blocks with the size of 4 were written into the paper sheets, then the papers were randomly picked (with replacement) and the chain of randomization was built until the desired sample size was reached.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The study samples and clinical caregivers are not aware of the drug or pharmacopoeia of the pills received

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Of Khalhkal University of Medical Sciences

##### Street address

Kashif1, Shahid Bakri Ave

##### City

Khalkhal

##### Province

Ardabil

##### Postal code

5681933491

#### Approval date

2019-09-04, 1398/06/13

#### Ethics committee reference number

IR.KHALUMS.REC.1398.001

## Health conditions studied

### 1

#### Description of health condition studied

Sexual function

#### ICD-10 code

F52.0

#### ICD-10 code description

Lack or loss of sexual desire

## Primary outcomes

### 1

#### Description

Sexual function

#### Timepoint

Before and 35 days after intervention

#### Method of measurement

Female Sexual Function Index questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the intervention group, the subjects will consume 35 tablets containing 300 mg of palm pollen daily.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In this group, the subjects will consume

35 placebo tablets daily.

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Khalkhal Health Centers

**Full name of responsible person**

Roghayeh Salmani

**Street address**

Kashif 1, Shahid Bakri Street

**City**

Khalkhal

**Province**

Ardabil

**Postal code**

5681933491

**Phone**

+98 45 2423 3017

**Email**

R.Salmani@Khalums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

The Khalkhal School of Medical Sciences

**Full name of responsible person**

Dr Bagher Hayati

**Street address**

The Khalkhal School of Medical Sciences. Shahid  
Mozafar Azizi Ave.

**City**

Khalkhal

**Province**

Ardabil

**Postal code**

5681854357

**Phone**

+98 45 3242 2002

**Email**

Bagher.hayati90@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

The Khalkhal School 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**

The Khalkhal School of Medical Sciences

**Full name of responsible person**

Roghayeh Salmani

**Position**

Faculty

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Kashf1,Shahid bakeri Ave

**City**

khalkhal

**Province**

Ardabil

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**Phone**

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**Email**

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**Person responsible for scientific inquiries**

**Contact**

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**Contact**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Questionnaire and spss file

**When the data will become available and for how long**

Starting data access period, one year after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Access to the results of the analysis

**From where data/document is obtainable**

R.Salmani@khalums.ac.ir Salmany.Ro@gmail.com

**What processes are involved for a request to access data/document**

Data request or file, follow up one week after request

**Comments**