Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of pollen Capsules on the sexual function of infertile couples referring to the infertility clinic of Jahrom city in 2019

Protocol summary

Study aim
Determining the effect of pollen on sexual function of infertile couples

Design
A clinical trial with a control and randomization group based on the number table, with parallel and double-blind groups of phase 2, will be performed on 128 people.

Settings and conduct
This double-blind randomized controlled trial (participants and researcher) will be performed on 128 infertile women and their husbands referred to Jahrom Infertility Clinic. In the intervention group, 300 mg capsule of date pollen capsule will be given daily for one month and in the same way to the placebo control group. One month later, the questionnaire will be completed and compared again by the participants.

Participants/Inclusion and exclusion criteria
nfertile women who have not had a history of pregnancy after 12 months of intercourse without the use of contraceptives. Be married and have sex at least once a month, be Iranian, have a basic education, be between the ages of 15 and 49, have not experienced any traumatic or stressful events in the last six months, have no history of hypothyroidism and chronic diseases that affect performance Be sexually effective, addicted to drugs and smoking by the research unit or his wife, allergies to pollen and other medicinal plants

Intervention groups
The experimental group of pollen-date plant diet with a dose of 300 mg in capsules will be given for one month. The control group will be given a placebo capsule at a dose of 300 mg for one month.

Main outcome variables
Sexual desire, sexual arousal, orgasm, relationship satisfaction, intercourse pain, general sexual function in infertile women. Erectile function, desire, orgasm, sexual satisfaction, general satisfaction in infertile women

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200925048834N1**
Registration date: **2020-10-07, 1399/07/16**
Registration timing: **retrospective**

Last update: **2020-10-07, 1399/07/16**
Update count: **0**

Registration date
2020-10-07, 1399/07/16

Registrant information

Name
Fateme sadat Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5433 1521

Email address
ftm.hoseini25@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-03-15, 1398/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of pollen Capsules on the sexual function of infertile couples referring to the infertility clinic of Jahrom city in 2019

Public title

The effect of pollen Capsules on the sexual function of infertile couples

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile women who have not been pregnant for one year without using any infertility prevention device. Getting married and having sex at least once a month Be Iranian Have basic literacy (reading and writing) Women in research units ranging in age from 15 to 49 years.

Exclusion criteria:

Experience some unfortunate or stressful events in the last six months by the research unit or its spouse Having a history of hypothyroidism and chronic diseases that affect the sexual function of infertile women and their husbands Drug and smoking addiction by the research unit or his / her spouse Allergy to plants and other medicinal plants

Age

From **15 years** old to **49 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was done by simple random allocation method, a table of random numbers was used to select the units. In this method, first the list of names of all infertile women is obtained, then each of them is assigned a score or number and using The required number of units was selected from the table of random numbers. And 64 couples were placed in each group. The study design will be parallel and both groups will be examined for sexual function. Double blind was also used in this study.

Blinding (investigator's opinion)

Double blinded

Blinding description

It was a double-blind method in which the subjects (participants) and observers did not know who was in which group.

Placebo

Used

Assignment

Parallel

Other design features

There is no case

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jahrom University of Medical science

Street address

Jahrom university of medical science, motahari blvd , jahrom

City

Jahrom

Province

Fars

Postal code

7414846199

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.JUMS.REC.1398.049

Health conditions studied

1

Description of health condition studied

sexual function

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 the intervention and after the end of the one-month period of capsule use

Method of measurement

male sexual function questionnaires and female sexual function questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group: Diet-pollen (pure) plant diet with a dose of 300 mg in capsules, will be given for one month

before the intervention, male sexual function questionnaires will be given to husbands and female sexual function questionnaire will be given to infertile women. One month during the phone call and follow-up questionnaire will be given to individuals to complete the data.

Category

Prevention

2

Description

The control group of placebo at a dose of 300 mg daily in capsules will be given for one month before the intervention. Men's sexual function questionnaires will be given to husbands and women 's sexual function questionnaires will be given to infertile women. Questionnaires will be given to individuals to complete the data

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Clinic of Jahrom city

Full name of responsible person

Safieh Jamali

Street address

janbazan blvd.

City

Jahrom

Province

Fars

Postal code

7414846199

Phone

+98 71 5423 0012

Email

safieh_jamali@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavous Sahljoo

Street address

Motahari blvd, jahrom university of medical science

City

Jahrom

Province

Fars

Postal code

7414846199

Phone

+98 71 5433 6085

Email

pshora2014@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Safieh Jamali

Position

Faculty of Jahrom University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Jahrom. Jahrom university of medical science

City

Jahrom

Province

Fars

Postal code

7414846199

Phone

+98 71 5433 1521

Fax

Email

Ftm.hoseini25@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Safieh Jamali

Position

Faculty of Jahrom University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Gynecology and Obstetrics

Street address
Jahrom. Jahrom university of medical science

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 71 5423 5529

Fax

Email
Ftm.hoseini25@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Fateme Hosseini

Position
Medical student(intern)

Latest degree
A Level or less

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Jahrom. Jahrom university of medical science

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 71 5433 1521

Fax

Email
Ftm.hoseini25@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available