

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of squill Oil on the dyspareunia and sexual satisfaction in menopause women

#### Protocol summary

##### Study aim

the Effect of Squill Oil on the Dyspareunia and Sexual Satisfaction in Menopause Women

##### Design

A clinical trial with a control group, with a parallel, blind, randomized clinical trial. Random Type: Simple by using odd and even numbers. Sample size based on estimation with a power of 90% and a 95% confidence coefficient of 26 were calculated for each group, with a probability of 20% of the sample drop, 30 people in each group were considered

##### Settings and conduct

Qualified samples referring to health canters are randomly divided into two groups. Oils have similar appearance and they are placed into similar boxes by Pharmacist. Only after the end of the study, the name and characteristic of the subject that is written on the box will be revealed. The researcher, supplier, data collector, and data analysis will not be informed of the type of intervention received.

##### Participants/Inclusion and exclusion criteria

45-65year, complaining of dyspareunia. Exit criteria: Vaginal infection (bacterial vaginosis, trichomonas), any major genital disease (PID, uterine prolapse, cystocele, rectocele), hormone therapy, use of phytoestrogen drugs.

##### Intervention groups

In the intervention group for 4 weeks, 1 to 3 times a week, and 5 minutes before having sex, 3 cc (equivalent to one teaspoon) should be rubbed gently and roundly on clitoral area and vagina. In the control group, olive oil for 4 weeks, 1 to 3 times a week and 5 minutes before having sex, 3 cc (equivalent to one teaspoon) should be rubbed gently and roundly on clitoral area and vagina.

##### Main outcome variables

The primary outcome is dyspareunia and the secondary outcome is sexual satisfaction that measured by the relevant questionnaires. Time point: Before intervention, 4 weeks after the intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170430033718N4**

Registration date: **2019-03-17, 1397/12/26**

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

Last update: **2019-03-17, 1397/12/26**

Update count: **0**

##### Registration date

2019-03-17, 1397/12/26

##### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 936 795 8503

##### Email address

karimifr941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-16, 1397/12/25

##### Expected recruitment end date

2019-06-15, 1398/03/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of squill Oil on the dyspareunia and sexual

satisfaction in menopause women

### Public title

The effect of Squill Oil on the dyspareunia and sexual satisfaction in menopause women

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Giving a written consent Having literacy Being Iranian and living in Mashhad Age 45 to 65 years Married and having an intact marriage Do not have chronic medical history that affect on sexual function Having sex Pass at least one year from the last menstruation Complaints from the dyspareunia (earning at least one rating based on the Marinf scale score)

#### Exclusion criteria:

Vaginal infection (vaginose bacteriana, trichomonas) Any major diseases of the genital tract (PID, uterine prolapse, cystocele, rectocele) Hormone therapy or sexual hormones consumption within 8 weeks before the study Smoking and Alcohol Women with uterine bleeding or spotting and the high consumption of other phytoestrogenic drugs (soy, red clover, fenugreek, Vitex agnus) over the past month

### Age

From **45 years** old to **65 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Data analyser

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Envelopes will be prepared and printed by a member of the research team and random numbers with the help of Randomize.com and will be placed inside the envelope. The envelopes will be closed and its contents are not visible from the outside. Then, the purpose of the study is explained to the person who follows the conditions, and the person, if desired, signs the informed consent form and removes an envelope, then opens it and, based on the contents of the envelope, enters into the intervention or control group.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

The preparation of the envelopes will be done by the person not involved in the collection and analysis of the data. In this way, the participants, prescriber, data collector and data analyzer will not be aware of the type of intervention received.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Mashhad Faculty of Nursing and Midwifery, Ebne Sina St, Doktora Crossroads

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

91778774896

#### Approval date

2019-03-09, 1397/12/18

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1397.082

## Health conditions studied

### 1

#### Description of health condition studied

dyspareunia

#### ICD-10 code

N94.1

#### ICD-10 code description

Dyspareunia

## Primary outcomes

### 1

#### Description

dyspareunia

#### Timepoint

Before intervention and 4 weeks after the intervention

#### Method of measurement

Marinf dyspareunia scale

### 2

#### Description

sexual satisfaction

#### Timepoint

Before intervention and 4 weeks after the intervention

#### Method of measurement

sabbatsberg sexual satisfaction questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: for 4 weeks, 1 to 3 times a week, and 5 minutes before having sex, 3 cc (equivalent to one teaspoon) should be rubbed gently and roundly on clitoral area and vagina

#### Category

Treatment - Drugs

### 2

#### Description

Control group: olive oil for 4 weeks, 1 to 3 times a week and 5 minutes before having sex, 3 cc (equivalent to one teaspoon) should be rubbed gently and roundly on clitoral area and vagina

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Banafsheh health center

##### Full name of responsible person

Dr Hashem Alizadeh

##### Street address

No. 3, Sajedi Ave., Mashhad Town

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9876540987

##### Phone

+98 51 3767 3922

##### Email

farzanekarimi83@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Abkou health center

##### Full name of responsible person

Dr Alizadeh

##### Street address

Janbaz Ave., Mashhad Town

##### City

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##### Province

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##### Postal code

6758940987

#### Phone

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#### Email

farzanekarimi83@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences, Vice chancellor for research

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraisly Building, Daneshgah St

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9876543213

##### Phone

+98 51 3879 6405

##### Email

farzanekarimi83@gmail.com

#### Grant name

#### Grant code / Reference number

971309

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

Yes

#### Title of funding source

Mashhad University of Medical Sciences, Vice chancellor for research

#### 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

School of Nursing and Midwifery

##### Full name of responsible person

Farzane Karimi

##### Position

Masters of Midwifery

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

**Street address**

Mashhad Faculty of Nursing and Midwifery, Ebne Sina  
St, Doktora Crossroads

**City**

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**Email**

karimifr941@mums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

School of Nursing and Midwifery

**Full name of responsible person**

Rahele Babazadeh

**Position**

Assiatant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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**Email**

babazader@mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

School of Nursing and Midwifery

**Full name of responsible person**

Farzane Karimi

**Position**

masters degree

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

**Street address**

Mashhad Faculty of Nursing and Midwifery, Ebne Sina  
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**Postal code**

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**Phone**

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**Email**

karimifr941@mums.ac.ir

**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