

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Squill oil on sexual function in females of reproductive age

#### Protocol summary

##### Summary

It is a randomized, double-blind clinical trial with two groups of experimental and control. Population study is females of reproductive age in two 30-persons groups who referred to midwifery clinics in Mashhad. Researcher selects all women aged 15 to 45 years old who receive midwifery care from the chosen clinic (convenience sampling). First, the researcher explains about the object of the study, implementation and the way of answering the questions. After obtaining consent from all subjects and ensure them to keep their information confidential, a pretest is taken. women who satisfy inclusion criteria and the score of their sexual function is less than 28 enter the study. Then they will be allocated to placebo and experimental groups randomly (30 persons in each group). For this reason, olive oil and Squill oil will be placed in a box (having code and similar together) and each matched-pairs picks up the medication herself, therefore the researcher is not aware of the oil type (double-blind). Then a training pamphlet will be given to the subjects explaining the way of using the oil, the anatomy of reproductive system and clitoris area in simple words and using pictures. Subjects should use the oil for 4 weeks, 2 -3 drops of oil should be rubbed gently and roundly on clitoral area 5 minutes before having sex (sensitive organ located above the urethra). According to the checklist prepared before, subjects will be followed up with phone call and their information including the number of having sex, the number of time they used oil, the amount of oil they used and its side effect will be recorded each weak. At the end of four weeks posttest will be taken from the subjects using the Female Sexual Function Index (FSFI) and sexual function of two groups before and after the intervention will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017051033897N1**

Registration date: **2017-09-29, 1396/07/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-29, 1396/07/07

##### Registrant information

###### Name

Maryam Abbasi Pirooz

###### Name of organization / entity

Mashhad University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3879 6405

###### Email address

abbasipm941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2017-07-09, 1396/04/18

##### Expected recruitment end date

2017-08-09, 1396/05/18

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Squill oil on sexual function in females of reproductive age

##### Public title

sexual function in females of reproductive age

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 15 to 45 years old; living with husband at least for 6 months; Be married and the only wife of her spouse; Lives with her spouse at the moment; The scores of Sexual function are less than 28 Exclusion criteria: Pregnant or three months after delivery; Addiction to drugs or alcohol in any of couple; Research Unit or her husband has any disabilities; physical or scroll problem; The history of infertility

**Age**

From **15 years** old to **45 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Qualified samples are randomly divided into two groups of 30 by removing even or odd ball from the bag. Therefore, if the subject draw even ball, she receives box A, otherwise she receives box B. 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

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

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

**City**

Mashhad

**Postal code**

9137913199

**Approval date**

2017-06-14, 1396/03/24

**Ethics committee reference number**

IR.MUMS.REC.1396.64

**Health conditions studied****1****Description of health condition studied**

Function sexual

**ICD-10 code**

F59.2

**ICD-10 code description**

Unspecified sexual dysfunction, not caused by organic disorder or disease

**Primary outcomes****1****Description**

sexual function

**Timepoint**

Before intervention,4 weeks after of treatment

**Method of measurement**

sexual function questionnaire(FSFI)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: squill oil should be rubbed the clitoris region for 2 to 3 drops 5 minues be fore sex

**Category**

Placebo

**2****Description**

control group: olive oil should be rubbed in to the clitoris region for 2 to 3 drops 5 minutes before sex

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Quaem hospital

**Full name of responsible person**

Efat koohjani

**Street address**

Ahmadabad st

**City**

Mashhad

## 2

### Recruitment center

**Name of recruitment center**

Emam Reza hospital

**Full name of responsible person**

Kazem Shabani

**Street address**

Ebnesina st

**City**

Mashhad

St, Doktora Crossroads

**City**

Mashhad

**Postal code**

91778774896

**Phone**

+98 518796405

**Fax**

**Email**

abbasipm941@mums.ac.ir

**Web page address**

## 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, Ghoraishy Building, Daneshgah St

**City**

Mashhad

**Grant name**

الف

**Grant code / Reference number**

951643

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

School of Nursing and Midwifery

**Full name of responsible person**

Maryam Abbasi Pirooz

**Position**

Masters of Midwifery

**Other areas of specialty/work**

**Street address**

Mashhad Faculty of Nursing and Midwifery, Ebne Sina

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

School of Nursing and Midwifery

**Full name of responsible person**

khadije Mirzaii

**Position**

PhD of Midwifery

**Other areas of specialty/work**

**Street address**

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

**City**

Mashhad

**Postal code**

9138813944

**Phone**

+98 51 3841 3008

**Fax**

+98 38413006

**Email**

mirzaiikh@mums.ac.ir

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

School of Nursing and Midwifery

**Full name of responsible person**

Maryam Abbasi Pirooz

**Position**

Master of health Fertility

**Other areas of specialty/work**

**Street address**

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

**City**

Mashhad

**Postal code**

9177874896

**Phone**

+98 51 3879 6405

**Fax**

**Email**

abbasipm941@mums.ac.ir

**Web page address**

## **Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*