

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)

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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

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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

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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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