

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of *Crocus sativus* on happiness and sexual function among menopausal women

Protocol summary

Summary

This study will be aimed to examine the effect of taking *Crocus Sativus* capsule in production of happiness and treatment of sexual disorder menopausal 45 to 60 year old women. In this single-blind clinical trial, the method of sampling will be convenience sampling. So that, 40 menopausal qualified women who have blood pressure below 160/110, don't take the antidepressant or tranquilizers and don't have suspicious lump in their breast examination, will be allocated in two groups of receiver of taking *Crocus Sativus* capsules or placebo. To hide the allocation, these capsules will be placed inside the numbering consecutive sealed opaque envelope by other research partner who is uninvolved in the sampling. Afterwards, women will be randomly divided into two groups and will be given 28 *crocus sativus* 30 mg capsules or placebo to each of them to take daily. The researcher will be called once a week to women to be sure for regular take of capsules and after 4 weeks, will be called again and happiness and sexual function questionnaire will be re-completed by them.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050722099N2**

Registration date: **2015-09-11, 1394/06/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-11, 1394/06/20

Registrant information

Name

mahboobeh ghorbani

Name of organization / entity

North Khorasan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 3228 9019

Email address

ghorbani.mahboobeh@gmail.com

Recruitment status

Recruitment complete

Funding source

North Khorasan University of Medical Sciences

Expected recruitment start date

2015-08-11, 1394/05/20

Expected recruitment end date

2016-02-09, 1394/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Crocus sativus* on happiness and sexual function among menopausal women

Public title

The effect of *Crocus Sativus* in production of happiness and treatment of sexual disorders among menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Iranian Muslims women; 45 to 60 year old women; Fifth grade of Elementary School (in Iran educational system); Married women; Women who passed at least 12 month after the last menstrual period or had more than 40 FSH; Women with natural menopause. Exclusion criteria: Getting the Estrogen/

Progesterone Hormone in the last 3 months; spotting in the last year; Using tobacco products (drugs, cigarette, hookah) or alcohol; using of drug/drugs to decrease menopausal symptoms or tranquilizers, antidepressants and anticoagulants in the past month; Having blood pressure more than 160/110; Having stressful life event in the past 6 months; Detecting of a lump or an abnormality in the breast examination or women with malignancy.

Age

From **49 years** old to **34 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

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

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Vice Chancellor for Research of North Khorasan
University of Medical Sciences

Street address

Vice Chancellor for Research of North Khorasan
University of Medical Sciences , Shahid Mofakhar
Alley, Kargar Square, Bojnord

City

Bojnord

Postal code**Approval date**

2015-06-21, 1394/03/31

Ethics committee reference number

IR.nkumf.rec.1394.c

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

sexual function

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction, not caused by organic disorder or disease

2**Description of health condition studied**

Happiness

ICD-10 code

F38

ICD-10 code description

Other mood [affective] disorders

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

Happiness

Timepoint

Before intervention and 4 weeks after taking the capsules.

Method of measurement

Oxford Happiness Inventory(OHI)

2**Description**

Sexual Function

Timepoint

Before intervention and 4 weeks after taking the capsules.

Method of measurement

Female Sexual Function Index(FSFI)

Secondary outcomes

empty

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

The interventional group: be taken daily 30 mg oral crocus sativus capsules for 28 days.

Category

Treatment - Drugs

2**Description**

The control group: be taken daily 30 mg placebo capsules for 28 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Mahboobeh Ghorbani

Street address

Imam Reza Clinic , Khoramshahr Square , Bojnord .

City

Bojnord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of North Khorasan
University of Medical Sciences

Full name of responsible person

Dr. Alireza Golshan

Street address

Vice Chancellor for Research of North Khorasan
University of Medical Sciences , Shahid Mofakhar
Alley, Kargar Square, Bojnord

City

Bojnord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of North Khorasan
University of Medical Sciences

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

Faculty of Nursing and Midwifery

Full name of responsible person

Mahboobeh Ghorbani

Position

Instructor of Midwifery

Other areas of specialty/work

Street address

Faculty of Nursing , Midwifery and Medicine, Alghadir,
Shahriar Street, Bojnord.

City

Bojnord

Postal code

Phone

+98 58 3229 7096

Fax

Email

ghorbani.mahboobeh@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery

Full name of responsible person

Mahboobeh Ghorbani

Position

Instructor of Midwifery

Other areas of specialty/work

Street address

Faculty of Nursing , Midwifery and Medicine, Alghadir,
Shahriar Street, Bojnord

City

Bojnord

Postal code

Phone

+98 58 3228 9019

Fax

Email

ghorbani.mahboobeh@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing and Midwifery

Full name of responsible person

Mahboobeh Ghorbani

Position

Instructor of Midwifery

Other areas of specialty/work

Street address

Faculty of Nursing , Midwifery and Medicine, Alghadir,
Shahriar Street, Bojnord

City

Bojnord

Postal code

Phone

+98 58 3228 9019

Fax

Email

ghorbani.mahboobeh@gmail.com

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