Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 sextual 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 blew 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 sextual 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 sextual disorders among menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Iranian Muslims women;45 to 60 year old women;Fifth grade of Elementray School (in Iran educational sysytem);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 criteri:Getting the Estrogen/

Progestin Hormone in the last 3 month;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 month;Detecting of a lump or an abnormality in the breast examination or women with malignancecy.

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

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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