Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

the effect of saffron(crocus sativus) on female sexual function in reproductive age

Protocol summary

Summary

This study is a double blind clinical trial with placebo control groups that is conducted to determine the effect of saffron on female sexual function in reproductive age. The study population consisted of 80 women 39-18 years old in the health and medical centers which are covered by Tehran University of Medical Sciences. Among of them persons who have the inclusion criteria would have to be selected as sample. Inclusion criteria for the study included marital status, age being 39-18 years, not pregnant, not breastfeeding, minimal literacy, lack of erectile dysfunction in wife .Exclusion criteria included lack of desire to continue taking the drug, the occurrence of pregnancy During the study, adverse stressful life events (death of a relative). They then completed a questionnaire of Female sexual function, in the presence of sexual dysfunction will be included in the study and randomly assigned to undergoing the experimental groups, or controlled and receive capsule of Saffron (15 mg twice daily) or placebo for a period of 8weeks . At the end of the week 4 and after the intervention (end of week 8), sexual function will be assessed using the same questionnaire again. If these results prove the effectiveness of saffron in treating impotence, it can be used to treat female sexual function problems.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206265912N5**
Registration date: **2013-10-13, 1392/07/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-10-13, 1392/07/21

Registrant information

Name
Mandana Mir Mohammad Ali Ei
Name of organization / entity
Tehran University of Medical Scinces
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Recruitment status

Recruitment complete

Funding source

Deputy of Research/ Tehran University of Medical Sciences

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of saffron(crocus sativus) on female sexual function in reproductive age

Public title

the effect of saffron(crocus sativus) on female sexual function in reproductive age

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women age 18-39 years; Iranian; Being married; No pregnancy Lack of breastfeeding; The ability of Reading and writing; Lack of diseases affecting sexual

function in person or her spouse; Lack of using drugs influence sexual function in person or her spouse; Lack of sexual dysfunction in her spouse;Not be multi partner her spouse; Not used hormonal drugs in recent months; Not used drugs in the past 6 months; Lack of allergy to herbal medicine; Lack of participation in other similar studies. Exclusion criteria: Lack of volunteers willing to continue taking drug; The occurrence of pregnancy during the study; Symptoms of allergy medication; Stressful life event.

Age
From **18 years** old to **39 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Science

Street address
Tehran University of Medical Science, Pur Sina street, Qods street,Keshavarz Bulvar, Tehran

City
Tehran

Postal code

Approval date
2013-07-22, 1392/04/31

Ethics committee reference number
92-01-99021934-90181

Health conditions studied

1

Description of health condition studied
female sexual dysfunction

ICD-10 code
F52.8

ICD-10 code description
other sexual dysfunction, not caused by organic disorder or disease

Primary outcomes

1

Description
Desire

Timepoint
Before intervention/ 4 week after intervention/8week after intervention

Method of measurement
Standardized questionnaire FSFI

2

Description
Excitement

Timepoint
Before intervention/ 4 week after intervention/ 8 week after intervention

Method of measurement
Standardized questionnaire FSFI

3

Description
Lubricaton

Timepoint
Before intervention/ 4 week after intervention/ 8 week after intervention

Method of measurement
Standardized questionnaire FSFI

4

Description
Orgasem

Timepoint
Before intervention/ 4 week after intervention/ 8 week after intervention

Method of measurement
Standardized questionnaire FSFI

5

Description
Sexual Satisfaction

Timepoint
Before intervention/ 4 week after intervention/ 8 week after intervention

Method of measurement
Standardized questionnaire FSFI

6

Description
Dysparonia

Timepoint
Before intervention/ 4 week after intervention/ 8 week

after intervention

Method of measurement

Standardized questionnaire FSFI

Secondary outcomes

empty

Intervention groups

1

Description

Saffron Ex tract/ Oral Capsul 15mg/ Twice a day/ For 8 week

Category

Treatment - Drugs

2

Description

Placebo/ No Action/Oral Placebo Capsul/ Twice a day for 8 week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers Of Arak University Of Medical Sciense

Full name of responsible person

Mr Rahmati

Street address

Phaze 2, Shahrake Shahid Beheshti, Hepco Street, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nursing & Midwifery Care Research Center

Full name of responsible person

Dr.Reza Negarandeh

Street address

Nursing and Midwifery Care Research Center, School of Nursing & Midwifery, East Nosrat Street,Tohid Squer

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nursing & Midwifery Care Research Center

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

Nursing &Midwifery Faculty - Tehran University Of Medical Science

Full name of responsible person

Mandana Mirmohama Ali Ei

Position

Hayat Journal

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