

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6692 7171

##### Email address

mirmohammad@tums.ac.ir

#### 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 Science

##### 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

##### Street address

Nursing &Midwifery Faculty - Tehran University Of Medical Science/Tohid square ,East Nosrat

##### City

Tehran

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+98 21 6692 7171

##### Fax

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mirmohamad1@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Mandana Mirmohamad Ali Ei

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Nursing &Midwifery Faculty - Tehran University Of  
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**Full name of responsible person**

Mandana Mirmohama Aali Ei

**Position**

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**Postal code****Phone**

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**Fax****Email**

mirmohamad1@yahoo.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*