

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Crocus Sativus L. on sexual dysfunction induced by Selective Serotonin Reuptake Inhibitors in male: a clinical trial

#### Protocol summary

##### Summary

Our objective is to assess efficacy of Cap. saffron in the treatment of sexual dysfunction induced by Selective Serotonin Reuptake Inhibitors. Forty patients with diagnosis of major depression who have already received Selective Serotonin Reuptake Inhibitors for 4 weeks will be entered into a 4-week double blind randomised trial. One group will receive Cap Saffron (30 mg/day) and another group will receive Cap Placebo. They will be assessed by international index of Erectile Function every two weeks for one month.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138711121556N3**  
Registration date: **2009-02-11, 1387/11/23**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2009-02-11, 1387/11/23

##### Registrant information

##### Name

Shahin Akhondzadeh

##### Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5541 2222

##### Email address

s.akhond@sina.tums.ac.ir

#### Recruitment status

##### Recruitment complete

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2009-02-20, 1387/12/02

##### Expected recruitment end date

2010-02-20, 1388/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Crocus Sativus L. on sexual dysfunction induced by Selective Serotonin Reuptake Inhibitors in male: a clinical trial

##### Public title

Saffron and decrease of sexual dysfunction induced by fluoxetine

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: at least 4 weeks usage of fluoxetine before study, do not use any psychotherapeutics except Selective Serotonin Reuptake Inhibitors, lack of chronic and organic disorders including cardiovascular diseases, informed consent. Exclusion Criteria: substance dependence, organic disorders, other psychiatric comorbidity including bipolar disorder, use of psychotropic drugs.

##### Age

From **20 years** old to **45 years** old

##### Gender

Male

##### Phase

2

#### Groups that have been masked

No information

### Sample size

Target sample size: 40

### 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 Sciences

##### Street address

Tehran University of Medical Sciences, Keshavarz Blv.

##### City

Tehran

##### Postal code

#### Approval date

empty

#### Ethics committee reference number

8145

## Health conditions studied

### 1

#### Description of health condition studied

Sexual dysfunction

#### ICD-10 code

F52

#### ICD-10 code description

Lack or loss of sexual desire

## Primary outcomes

### 1

#### Description

Score of international index of Erectile Function

#### Timepoint

every two weeks

#### Method of measurement

use of international index of Erectile Function

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Cap Saffron 15 mg twice per day as intervention group

#### Category

empty

### 2

#### Description

Cap Placebo twice per day as control group

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Roozbeh Psychiatric Hospital

##### Full name of responsible person

Dr. Firoozeh Raisi

##### Street address

Roozbeh Psychiatric Hospital, South Kargar Street

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Akbar Fotouhi

##### Street address

Tehran University of Medical Sciences, Keshavarz Blv

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran 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

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

Ph.D., Prof. of Clinical Psychopharmacology

**Other areas of specialty/work****Street address**

Roozbeh Psychiatric Hospital

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran university of Medical sciences

**Full name of responsible person**

Prof. shahin akhondzadeh

**Position**

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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*