

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

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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

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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**

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Prof. shahin akhondzadeh

Position

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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