Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Summary
Our objective is to assess efficacy of Cap. saffron in the treament of sexual dysfunction induced by Selective Seretonin Reuptake Inhibitors. Forthy patients with diagnosis of major depression who have already received Selective Seretonin 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
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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 Seretonin Reuptake Inhibitors in male: a clinical trial

Public title
Saffron and decrease of sexual dysfunction induced by fluoxetin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: at least 4 weeks usage of fluoxetin before study, do not use any psychotherapeutics except Selective Seretonin Reuptake Inhibitors, lack of chronic and organic disorders including cardiovascular diseases, informed consent. Exclusion Criteria: substance dependence, organic disorders, other psychiatric comorbidity including biploar 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

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Tehran University of Medical Sciences, Keshavarz Blv

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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
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Prof. Shahin Akhondzadeh
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Ph.D., Prof. of Clinical Psychopharmacology
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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