Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 2026

The effect of Crocus sativus on sexual dysfunction in female referred to Rouzbeh and Imam Khomeini Hospital

Protocol summary

Study aim
Comparing the effect of Crocus sativus with placebo in treatment of female sexual dysfunction
Design
Randomized placebo-controlled clinical trial
Settings and conduct
This randomized clinical trial will be conducted among women with sexual dysfunction attending Arash Hospital, Tehran, Iran and Imam Khomeini Hospital, Tehran, Iran in 2018-2019. The participants, physicians and evaluators will not know the grouping
Participants/Inclusion and exclusion criteria
Inclusion criteria: women with sexual dysfunction; married with stable marriage; age between 18 to 45 years; ability to read and write; score 16 or less on FSFI
Exclusion criteria: pregnancy; breastfeeding;menopause;any life threatening medical disease; depression; receiving medications affecting sexual desire and function including antidepressants, ASA and anticoagulants.
Intervention groups
Capsule Crocus sativus 15 mg BID for 6 weeks as intervention group
Main outcome variables
Severity of sexual dysfunction

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20090117001556N110**
Registration date: **2018-07-25, 1397/05/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-25, 1397/05/03**
Update count: **0**
Registration date
2018-07-25, 1397/05/03

Registrant information
Name
Shahin Akhondzadeh
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Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-07-22, 1397/04/31
Expected recruitment end date
2020-07-20, 1399/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Crocus sativus on sexual dysfunction in female referred to Rouzbeh and Imam Khomeini Hospital

Public title
The effect of Crocus sativus on sexual dysfunction in women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-40 Married woman with stable marriage

Having score 16 and less in Female Sexual Function Index The ability of Reading and writing

Exclusion criteria:

Pregnancy or breastfeeding Menopause Any life threatening medical disease Depression Receiving medications affecting sexual desire and function(including antidepressants, aspirin, anticoagulants)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

By computerized randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Similarity of placebo and medication. Participants, care provider and investigator are blinded in this study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Blv.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-07-14, 1397/04/23

Ethics committee reference number

IR.TUMS.VCR.REC.1397.223

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes

1

Description

Severity of sexual dysfunction

Timepoint

Baseline and weeks 3 and 6

Method of measurement

By Female sexual Function Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Crocus sativus 15 mg BID for 6 weeks

Category

Treatment - Drugs

2

Description

Control group: Capsule placebo BID for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash women's hospital

Full name of responsible person

Sahar Aslzadeh

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Arash women's hospital, Reslat highway, Tehranpars, Rashid Ave.

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Sponsors / Funding sources

1

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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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Prof. Shahin Akhondzadeh
Position
Prof. of Clinical Psychopharmacology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

In the final report

When the data will become available and for how long

from 2020 to 2025

To whom data/document is available

academic researchers

Under which criteria data/document could be used

all users should cite the resours of data

From where data/document is obtainable

prof. Shahin Akhondzadeh

What processes are involved for a request to access data/document

by E mail

Comments