

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of *Crocus sativus* on sexual dysfunction in male referred to Rouzbeh and Imamkhomeini Hospital : a clinical trial

Protocol summary

Study aim

The aim of this study is to assess the efficacy of saffron in the treatment of male erectile disorder

Design

Randomized double blind placebo-controlled clinical trial

Settings and conduct

The study will be conducted among the men with erectile disorder attending Roozbeh Hospital and Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: men with erectile disorder; married
Exclusion criteria: Endocrine disease; Diabetes mellitus; metabolic syndrome; severe depression

Intervention groups

Intervention group: saffron 15 mg BID for 6 weeks

Main outcome variables

Severity of erectile disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N109**
Registration date: **2018-07-24, 1397/05/02**
Registration timing: **prospective**

Last update: **2018-07-24, 1397/05/02**

Update count: **0**

Registration date

2018-07-24, 1397/05/02

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Rouzbeh 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

Expected recruitment start date

2018-08-05, 1397/05/14

Expected recruitment end date

2020-08-04, 1399/05/14

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 male referred to Rouzbeh and Imamkhomeini Hospital : a clinical trial

Public title

The effect of *Crocus sativus* on sexual dysfunction in male

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married men Erectile disorder Age between 18 to 45 years Score 25 or less on IIEF (International Index of Erectile Function)

Exclusion criteria:

Endocrine disease Severe depression Metabolic syndrome Diabetes Mellitus Coagulopathy Receiving warfarin Hypertension

Age

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

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Computerized randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, evaluators and clinicians will be blind to grouping

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.1397.222

Health conditions studied**1****Description of health condition studied**

En Male Erectile Disorder

ICD-10 code

F52.21

ICD-10 code description

Male erectile disorder

Primary outcomes**1****Description**

En severity of erectile disorder

Timepoint

Baseline and weeks 3 and 6

Method of measurement

By IIEF(International Index of Erectile Function)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:Crocus sativus 15 mg BID for 6 weeks

Category

Treatment - Drugs

2**Description**

Control group: Placebo for 6 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini hospital-Tehran

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

Imam Khomeini hospital, Keshavarz Blvd.

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2**Recruitment center****Name of recruitment center**

Roostbeh Hospital

Full name of responsible person

Prof. Shahin Akhondzadeh

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Roozbeh Hospital, South Kargar Street

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1333715914

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Ali Sahraian

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Msahrai@tums.ac.ir

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

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

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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

All data will be distributed through final report

When the data will become available and for how long

5 years-2020 to 2025

To whom data/document is available

All 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