

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Clinical trial of *Crocus sativus* L. supplementation on weight and depression among overweight women with depression compared with the placebo

Protocol summary

Summary

- Objective: To determine the effects of *Crocus sativus* L. supplementation on weight and depression among overweight women with depression compared with the control group. - Main inclusion criteria: Age 18 to 50 years, female gender, body mass index above 25, the diagnosis of depression - Main exclusion criteria: Taking drugs that affect on depression and weight, hormonal and metabolic disorders - Study population: The 18-50 years women with depression who are overweight or obese - Sample size: 50 - Intervention Study: *Crocus sativus* L. - Intervention duration: 12 weeks - Primary outcome or outcomes studied: Depression, weight, body mass index - Design of the study: fifty patients with mild depression (based on a semi-structured diagnostic interview and the Hamilton depression scale test) who are overweight or obese will participate in this double-blind, 12-week, placebo-controlled study. Participants will sign the informed consent form and then they will be randomly assigned to one of two groups receiving daily 30 mg of *Crocus sativus* L. capsules or placebo. The groups will be blinded by placebo to participants and will be blinded to researcher by coding. At the end, hypothesis of the study will be tested.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041916465N2**

Registration date: **2014-06-16, 1393/03/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-06-16, 1393/03/26

Registrant information

Name

Seyed-Ali Mostafavi

Name of organization / entity

Psychiatry Research Center/ Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 2002

Email address

mostafavi_a@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2016-03-18, 1394/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of *Crocus sativus* L. supplementation on weight and depression among overweight women with depression compared with the placebo

Public title

Evaluating the effects of *Crocus sativus* L. (Saffron) on weight and depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18 to 50 years; females; Body Mass Index above 25; patients with mild (minor) depression based on semi- structured diagnostic interview by a psychiatrist; to sign a consent form
Exclusion Criteria: Those who are taking antidepressants; severe (major) depression; psychotic depression or have suicidal thoughts; use of anti-inflammatory glucocorticoids, and steroids; those who take medicines to reduce appetite or weight; those with diabetes who are taking medications or insulin; those with heart disease or hypercholesterolemia who are taking medication (statins, fibrates, diuretics); those how are taking oral anti-inflammatory drugs corticosteroids or any drug that causes weight loss or gain; taking hormonal contraceptives; pregnancy and lactation; menopause; severe mental disorder; schizophrenia and bipolar; hypothyroidism; exercise professionals; those with special diets such as the diets for kidney disorders.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

Ethics Committee of Tehran University of Medical Sciences

Street address

Committee on Ethics in Medical Research, Research Council, Central Building of Tehran University of Medical Sciences, Keshavarz Blvd Tehran, Iran

City

Tehran

Postal code**Approval date**

2013-12-05, 1392/09/14

Ethics committee reference number

130/2045/92/3

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

Mild Depression

ICD-10 code

F32.0

ICD-10 code description

Mild depressive episode Two or three of the above symptoms are usually present. The patient is usually distressed by these but will probably be able to continue with most activities.

2**Description of health condition studied**

Moderate depression

ICD-10 code

F32.1

ICD-10 code description

Moderate depressive episode Four or more of the above symptoms are usually present and the patient is likely to have great difficulty in continuing with ordinary activities.

3**Description of health condition studied**

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

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

Weight

Timepoint

At baseline and at weeks 2, 4, 8 and 12 after the beginning of the study

Method of measurement

Standard scales Seca

2**Description**

Body Mass Index

Timepoint

At baseline and at weeks 2, 4, 8 and 12 after the beginning of the study

Method of measurement

kg/(m)²

3**Description**

Depression

Timepoint

At baseline and at weeks 2, 4, 8 and 12 after the beginning of the study

Method of measurement

Hamilton rating scale for depression

Secondary outcomes

empty

Intervention groups

1

Description

30 mg Crocus sativus L. capsules for 12 weeks

Category

Treatment - Drugs

2

Description

Placebo capsule for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Private weight loss clinic

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Harati-Zadeh

Street address

No. 608, Research Coordination Centre Office, Central Building of Tehran University of Medical Sciences, Qods St., Keshavarz Boulevard

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

Name of organization / entity

Psychiatric Research Center

Full name of responsible person

Seyed-Ali Mostafavi

Position

Ph.D by Research student

Other areas of specialty/work

Street address

Roozbeh Hospital, South Kargar St.

City

Tehran

Postal code

Phone

+98 21 5541 3540

Fax

Email

mostafavi.n80@hotmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Psychiatric Research Center

Full name of responsible person

Shahin Akhondzadeh

Position

Ph.D

Other areas of specialty/work

Street address

Roozbeh Hospital, South Kargar St.

City

Tehran

Postal code

Phone

+98 21 5541 3540

Fax

Email

s.akhond@neda.net

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Psychiatric Research Center

Full name of responsible person

Seyed-Ali Mostafavi

Position

Ph.D by Research student

Other areas of specialty/work

Street address

Roozbeh Hospital, South Kargar St.

City

Tehran

Postal code

Phone

+98 21 5541 3540

Fax

Email

mostafavi.n80@hotmail.com

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