

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the effect of *Crocus sativus* L. (Saffron) on appetite and weight of subjects with binge eating disorder: A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Evaluating the effect of *Crocus sativus* L. (Saffron) on appetite and weight of subjects with binge eating disorder

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

This study will be performed on patients attending Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals with binge eating disorder confirmed by the SCID-V semi-structured questionnaire - No specific diet - Normal physical activity - No drug or non-drug treatment. Exclusion criteria: Diabetes - Cancer - Drug addiction - Thyroid dysfunction - Drugs effective in appetite and weight - Taking psychiatric drugs - Stomach surgery or taking food supplements - Diagnosis of other eating disorders.

Intervention groups

Control group: patients take placebo capsules twice a day - Intervention group: patients take saffron capsules with a dose of 15 mg twice a day.

Main outcome variables

The severity of binge eating disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N149**

Registration date: **2023-04-04, 1402/01/15**

Registration timing: **prospective**

Last update: **2023-04-04, 1402/01/15**

Update count: **0**

Registration date

2023-04-04, 1402/01/15

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

s.akhond@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of *Crocus sativus* L. (Saffron) on appetite and weight of subjects with binge eating disorder: A randomized, double-blind, placebo-controlled clinical trial

Public title

The effect of saffron on binge eating disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Individuals with binge eating disorder confirmed by the SCID-V semi-structured questionnaire
No specific diet
Normal physical activity
No drug or non-drug treatment

Exclusion criteria:
Diabetes
Cancer
Drug addiction
Thyroid dysfunction
Drugs effective in appetite and weight
Taking psychiatric drugs
Stomach surgery or taking food supplements
Diagnosis of other eating disorders

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups).

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of School of Medicine, Tehran
University of Medical Sciences
Street address

Tehran University of Medical Sciences, Qhods St.,
Keshavarz Blvd.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2023-01-02, 1401/10/12

Ethics committee reference number
IR.TUMS.IKHC.REC.1401.454

Health conditions studied

1

Description of health condition studied
The severity of binge eating disorder

ICD-10 code
F50.02

ICD-10 code description
Anorexia nervosa, binge eating/purging type

Primary outcomes

1

Description
The severity of binge eating disorder

Timepoint
Baseline, and weeks 4, 8, 12

Method of measurement
By SCID-V semi-structured questionnaire - DASS-21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: patients take placebo capsules twice a day for three months.

Category
Placebo

2

Description
Intervention group: patients take saffron capsules with a dose of 15 mg twice a day for three months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Dr. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street, Tehran

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mohammadimr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Keshavarz Blvd.

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afotouhi@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

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

Dr. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Roozbeh Hospital, South Kargar Street, Tehran

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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

Yes - There is 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

The data will be distributed through final report

When the data will become available and for how long

5 years from 2023 to 2028

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Users should cite the resource 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