

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1333715914

**Phone**

+98 21 5541 2222

**Email**

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.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 5541 2222

**Email**

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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**Province**

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**Email**

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## Person responsible for scientific inquiries

### Contact

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Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Shahin Akhondzadeh

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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**