

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Assessment of additive effects of crocin in men with depression induced by amphetamine withdrawal

#### Protocol summary

##### Study aim

Additive effects of crocin on depression symptoms in men with moderate depression induced by amphetamine withdrawal admitted to Ibn-e-Sina Hospital, Mashhad

##### Design

A Randomized, Triple-Blind, Placebo-Controlled Clinical Trial Triple masking (Participant, Investigator, Outcomes Assessor and Statistician)

##### Settings and conduct

Patients referred to Ibn-e-sina hospital- Mashhad- Iran, after signing informed consent, will be randomly allocated to the following two groups. Placebo Group in which, patients (n=30) will receive placebo tablets and Crocin Group in which, patients (n=30) will receive Crocin 15 mg, daily, for 12 weeks. All subjects will receive the conventional depression therapy during study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: (1) Men with moderate depression induced by amphetamine withdrawal, (2) Being 20-50 years old, (3) Patient consent to participate in the study, (4) Not having specific physical (e.g. cancer, Acquired immunodeficiency syndrome (AIDS), Multiple Sclerosis (MS)) or mental illness, (5) Not having allergic to saffron/crocin Exclusion criteria: Lack of patient cooperation in Crocin consumption Having allergic reaction or intolerable side effect caused by crocin

##### Intervention groups

Placebo Group in which, patients (n=30) will receive placebo tablets and Crocin Group in which, patients (n=30) will receive Crocin 15 mg daily for 12 weeks.

##### Main outcome variables

Beck Depression Inventory (BDI) questionnaire and General Health Questionnaire (GHQ) will be completed before treatment (day 0) and at the end of weeks 4, 8 and 12 after starting treatment.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160804029191N3**

Registration date: **2021-12-02, 1400/09/11**

Registration timing: **prospective**

Last update: **2021-12-02, 1400/09/11**

Update count: **0**

##### Registration date

2021-12-02, 1400/09/11

##### Registrant information

##### Name

Vahideh Ghorani Sirjani

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3882 8565

##### Email address

ghoranisv921@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-21, 1400/11/01

##### Expected recruitment end date

2022-07-21, 1401/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Assessment of additive effects of crocin in men with depression induced by amphetamine withdrawal

## Public title

Effect of crocin on depression induced by amphetamine withdrawal

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Men with moderate depression induced by amphetamine withdrawal Being 20-50 years old Patient consent to participate in the study Not having specific physical (e.g. cancer, Acquired immunodeficiency syndrome (AIDS), Multiple Sclerosis (MS)) or mental illness Not having allergic to saffron/crocin

### Exclusion criteria:

Lack of patient cooperation in Crocin consumption Having allergic reaction or intolerable side effect caused by crocin

## Age

From **20 years** old to **50 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

Simple randomization method (using <https://www.Randomization.com-generated> sequence). In this method, using website <https://www.Randomization.com> that generates the random number sequences, the random number sequences are determined for the required sample size (n=30 in each group). Following, after patients enter the study based on the inclusion criteria, according to the list of the random number sequences generated, individuals are assigned to one of the intervention and placebo groups, and this continues until the number of patients in each group is completed.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

Drugs will be packed and labelled . No information on the randomization schedule or the contents of drug packs will be available to patients, investigators, care providers and outcomes assessors and they will be blinded. The patients will be blinded in the sense that they do not know whether they were receiving the placebo or crocin. They randomly assign to one of the two groups. The investigators doing the interventions will be blinded as to the contents of the drug using drugs labelling. Also care providers and outcomes assessors shall be blinded as to

what group the patient belongs to. One person in the project who does not belong to any of the groups of patients, investigators, care providers and outcomes assessors, will oversee on blinding method.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Faculty of Medicine, Ferdowsi University campus, Azadi square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

#### Approval date

2021-08-24, 1400/06/02

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.379

## Health conditions studied

### 1

#### Description of health condition studied

Depression

#### ICD-10 code

F33

#### ICD-10 code description

Recurrent depressive disorder

## Primary outcomes

### 1

#### Description

Beck Depression Inventory (BDI) questionnaire

#### Timepoint

Before treatment (day 0) and at the end of weeks 4, 8 and 12 after starting treatment

#### Method of measurement

Completion of the questionnaire by patient or researcher

### 2

#### Description

General Health Questionnaire (GHQ)

#### **Timepoint**

Before treatment (day 0) and at the end of weeks 4, 8 and 12 after starting treatment

#### **Method of measurement**

Completion of the questionnaire by patient or researcher

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Control group: In this group, patients (n=30) will receive placebo tablet (Containing Avicel, made by School of Pharmacy, Mashhad University of Medical Sciences), daily for 12 weeks.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Intervention group: In this group, patients (n=30) will receive 15 mg crocin tablet (made by School of Pharmacy, Mashhad University of Medical Sciences), daily for 12 weeks.

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Ibn-e-Sina Hospital

###### **Full name of responsible person**

Maedeh Kamrani

###### **Street address**

Horr-e-Ameli St., Ibn-e-Sina hospital

###### **City**

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Razavi Khorasan

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### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Mashhad University of Medical Sciences

##### **Full name of responsible person**

Majid Ghayour-Mobarhan

##### **Street address**

Ghoreshi department, Daneshgah Ave

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13944-91388

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p.relations@mums.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

###### **Full name of responsible person**

Ramin Rezaee

###### **Position**

Assistant Professor

###### **Latest degree**

Ph.D.

###### **Other areas of specialty/work**

Toxicology

###### **Street address**

Ibn Sina St., Imam Reza Hospital Square, Imam Reza Hospital

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Maedeh Kamrani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for updating data

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Mashhad University of Medical Sciences

**Full name of responsible person**

Vahideh Ghorani Sirjani

**Position**

Ph.D.

**Latest degree**

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**Other areas of specialty/work**

Physiology

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Dr. Vahideh Ghorani is committed to presenting all the achievements of the project in accordance with the framework of Mashhad University of Medical Sciences.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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