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)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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Position
Assistant Professor

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Specialist

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Psychiatrics

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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