

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of crocin supplementation on cognitive functions, craving and withdrawal syndrome in methadone maintenance treatment patients

Protocol summary

Study aim

The aim of this study is to determine the effects of crocin supplementation on cognitive functions, craving and withdrawal syndrome in methadone maintenance treatment patients

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Population and sample size: 60 eligible patients on methadone maintenance treatment referred to Soltan Mirahmad Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients on methadone maintenance treatment and aged 18 to 70 years will be included in this study. Exclusion criteria: Unwillingness to cooperate.

Intervention groups

Intervention: Patients will be assigned to receive either crocin (n=30) or placebo (n=30).

Main outcome variables

Craving and withdrawal syndrome (primary outcome), and cognitive functions (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170420033551N6**
Registration date: **2019-07-09, 1398/04/18**
Registration timing: **retrospective**

Last update: **2020-07-15, 1399/04/25**

Update count: **1**

Registration date

2019-07-09, 1398/04/18

Registrant information

Name

Amir Ghaderi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-19, 1398/02/29

Expected recruitment end date

2019-06-19, 1398/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of crocin supplementation on cognitive functions, craving and withdrawal syndrome in methadone maintenance treatment patients

Public title

Effect of crocin supplementation in treatment of methadone maintenance treatment patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients on methadone maintenance treatment Age of 18 to 70 years old Evaluated by the drug abuse section of the Structured Clinical Interview for DSM-IV Seeking for treatment

Exclusion criteria:
Unwillingness to cooperate Current severe depression and mania Psychosis Consumption of crocin, antioxidant, and anti-inflammatory supplements during the last 3 months High blood pressure Hypothyroidism or hyperthyroidism

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m²) and age (<40 and ≥40 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo has been used to achieve masking of participants and investigators. The researchers and patients will be concealed until the final analyses by a trained staff.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2019-04-08, 1398/01/19

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.012

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F19

ICD-10 code description

Other psychoactive substance related disorders

Primary outcomes

1

Description

Craving

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Desire for Drug Questionnaire (DDQ craving)

2

Description

Withdrawal syndrome

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Clinical opiate withdrawal symptoms (COWS)

Secondary outcomes

1

Description

Evaluation of cognitive function

Timepoint

At the baseline and after intervention (12 weeks)

Method of measurement

Cognitive function questionnaire

2

Description

Verba Fluency

Timepoint

At the baseline and after intervention (12 weeks)

Method of measurement

FAS task

3

Description

Speed Processing

Timepoint

At the baseline and after intervention (12 weeks)

Method of measurement

Digit Symbol and Trial Making Test (TMT)

4

Description

Memory

Timepoint

At the baseline and after intervention (12 weeks)

Method of measurement

Wechsler intelligence Scale (DGSP)

Intervention groups

1

Description

Intervention group: tablet of crocin, 15 mg, two oral tablet for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: placebo tablet, two oral tablet for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Soltan Mirahmad Clinic

Full name of responsible person

Amir Ghaderi

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Shahid Motahari Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Amir Ghaderi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Ph.D of addiction

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available