

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

A Clinical trial to assess the effect of crocin supplementation compared with the placebo on mental health parameters, metabolic profiles and genetic response in methadone maintenance treatment patients

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The aim of this study is to determine the effects of crocin supplementation on mental health parameters, metabolic profiles and genetic response in methadone maintenance treatment patients

Last update: **2019-09-15, 1398/06/24**

Update count: **1**

Registration date

2018-12-31, 1397/10/10

Design

Clinical trial with control group, parallel groups, double-blind (both patients and researchers), randomized, 60 patients, phase 2

Registrant information

Name

Amir Ghaderi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Settings and conduct

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

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients on methadone maintenance treatment and aged 18 to 60 years, Beck Depression Scores > 20 and Beck Anxiety > 15 will be included in this study. Exclusion criteria: Taking crocin, anti-inflammatory and antioxidant supplements during the last 3 months before the intervention, history of metabolic diseases including diabetes, hypertension, thyroid, and cardiovascular disease.

Expected recruitment start date

2018-12-13, 1397/09/22

Expected recruitment end date

2019-01-12, 1397/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

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

Scientific title

A Clinical trial to assess the effect of crocin supplementation compared with the placebo on mental health parameters, metabolic profiles and genetic response in methadone maintenance treatment patients

Main outcome variables

Mental health parameters (primary outcome), metabolic profiles and genetic response (secondary outcome)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170420033551N4**

Registration date: **2018-12-31, 1397/10/10**

Public title

Effect of crocin supplementation in treatment of methadone maintenance treatment patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Currently undergoing MMT and opioid dependence in the past year Age of 18 to 60 years old Evaluated by the drug abuse section of the Structured Clinical Interview for DSM-IV Beck Depression Scores > 20 and Beck Anxiety > 15 Seeking for treatment

Exclusion criteria:

Taking crocin, anti-inflammatory and antioxidant supplements during the last 3 months before the intervention. History of metabolic diseases including diabetes, hypertension, thyroid, and cardiovascular disease.

Age

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

Gender

Male

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed with simple method and random numbers generated by computer software (Stat Trek software) which choose the random numbers. Then, we consider the specific numbers for both groups. .

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo will be used to achieve participants and investigators masking. 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

2018-12-11, 1397/09/20

Ethics committee reference number

IR.KAUMS.REC.1397.006

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F19

ICD-10 code description

Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances

Primary outcomes

1

Description

Depression beck score

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Questionnaire

2

Description

Anxiety beck score

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Total antioxidant

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

HDL
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
Total cholesterol
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Triglycerides
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
Insulin
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Elisa kit

7

Description
Nitric oxide
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Spectrophotometry

8

Description
Hs-CRP
Timepoint
At the beginning of the study and after 8 weeks of

intervention
Method of measurement
Elisa kit

9

Description
Expressed levels of LL-1 gene
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
PCR

10

Description
Expressed levels of TNF- α gene
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
PCR

11

Description
Expressed levels of PPAR- γ
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
PCR

12

Description
Total glutathione
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
Spectrophotometry

13

Description
Malondialdehyde
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
Spectrophotometry

14

Description
Expressed levels of TGF- β gene
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
PCR

15

Description

Expressed levels of LDLR gene

Timepoint

At the beginning of the study and 8 weeks after intervention

Method of measurement

PCR

Intervention groups

1

Description

Intervention group: tablet of Crocin, 15 mg, two oral tablet for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo tablet, two oral tablet for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gholabchi Clinic

Full name of responsible person

Zatollah Asemi

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Shahid Rajaei 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

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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
No - There is not a plan to make this available
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