

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of crocin on weight gain in patients taking clozapine

Protocol summary

Study aim

The effect of crocin on weight gain in patients taking clozapine

Design

This study is a double-blind, randomized, placebo-controlled clinical trial. In this study, using purposive sampling method, 74 patients taking antipsychotic drugs admitted to Hejazi Hospital in Mashhad, who take clozapine for at least one month with the prescription of a psychiatrist, after completing the informed consent form of guardian or legal guardian and The patient himself will enter the study. Patients will then be randomly assigned to one of the drug or placebo groups (37 in each group)

Settings and conduct

The place of this research is Dr. Hejazi Psychiatric Hospital in Mashhad. It is a two-way blind study in which the people under study and evaluators are blind and the blinding is done by sealed envelopes

Participants/Inclusion and exclusion criteria

Admission requirements: 1) Patients taking clozapine who at least one month before the start of the study with a BMI greater than 25 or weight gain greater than 10% (2) Age range 20 to 60 years (3) Satisfaction of the patient and his guardian for the company Conditions of non-entry: (1) No entry of schizoaffective and bipolar patients (2) Non-pregnancy and lactation (3) Do not enter patients who are taking drugs that affect weight at the same time (4) Do not admit patients who are addicted to drugs, stimulants and alcohol (5) Lack of untreated medical condition affecting weight such as hypothyroidism (6) Dissatisfaction of the patient or her guardian to participate in the study

Intervention groups

Intervention group: Taking crocin 15 mg tablets twice a day for 8 weeks Control group: placebo tablets are prescribed twice a day for 8 weeks with appearance and protocol

Main outcome variables

Weight; Waist size and BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211202053250N2**

Registration date: **2022-07-24, 1401/05/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-24, 1401/05/02**

Update count: **0**

Registration date

2022-07-24, 1401/05/02

Registrant information

Name

Mahboubbeh eslamzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2721

Email address

eslamzadehmf@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-20, 1401/03/30

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of crocin on weight gain in patients taking

clozapine

Public title
The effect of crocin on weight gain in patients taking clozapine

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients taking clozapine for at least one month before the start of the study with a BMI greater than 25 or weight gain greater than 10% Age range 20 to 60 years Patient and guardian consent to participate in the study No entry of schizoaffective and bipolar patients No history of allergies to crocin No pregnancy and lactation Do not admit patients who are taking drugs that affect weight at the same time Do not admit patients who are addicted to drugs, stimulants and alcohol Lack of untreated medical condition affecting weight such as hypothyroidism
Exclusion criteria:
No patient entering below the age range of 20 years and above 60 years No entry of schizoaffective and bipolar patients Absence of pregnancy and lactation Do not admit patients who are taking drugs that affect weight at the same time Do not admit patients who are addicted to drugs, stimulants and alcohol Lack of untreated medical condition affecting weight such as hypothyroidism Patient dissatisfaction to participate in the study

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization will be done using the random block method. By using www.randomizer.org, randomization will be done using random blocks. In the optimization part, the list of random numbers will be generated as 37 blocks of 2. Based on that, people will be randomly assigned to one of the intervention and control groups using a sealed envelope

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, blinding will be done in relation to the participants in the research, researcher and data evaluator. The form of drugs and placebos is exactly the same, so the patient will not know the type of intervention. Also, the treating physician will not know the type of intervention. Therefore, the study will be conducted blindly. To evaluate the data, groups will be assigned a number instead of a name, so that the course

can be evaluated

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
Ibn Sina Psychiatric Hospital, Hore ameli Blvd, Ferdowsi Squaree
City
Mashhad
Province
Razavi Khorasan
Postal code
1394491388

Approval date
2022-05-15, 1401/02/25

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.083

Health conditions studied

1

Description of health condition studied
Weight gain
ICD-10 code
E66.9
ICD-10 code description
Simple obesity NOS

Primary outcomes

1

Description
Weight
Timepoint
It is measured in patients at time zero and at the end of weeks 4 and 8
Method of measurement
Balance

2

Description
Waist size
Timepoint
It is measured in patients at time zero and at the end of

weeks 4 and 8
Method of measurement
centimeter

3

Description

Positive and negative symptoms of schizophrenia

Timepoint

It is measured in patients at time zero and at the end of weeks 4 and 8

Method of measurement

PANSS Test

4

Description

Body Mass Index

Timepoint

It is measured in patients at time zero and at the end of weeks 4 and 8

Method of measurement

Height to weight ratio

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Taking 15 mg crocin tablets twice a day for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo tablets are prescribed twice a day for 8 weeks with appearance and protocol

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn-Sina Hospital

Full name of responsible person

Mahboubah Eslamzadeh

Street address

Ibn Sina Psychiatric Hospital, Hor Ameli Blvd.
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eslamzadehmq@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mubarrhan

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Grant name

Vice Chancellor for Research, Mashhad University of Medical Sciences

Grant code / Reference number

991936

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

Mahboubah Eslamzadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahboubbeh Eslamzadeh

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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

There is no more information

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