

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of the effect of crocin capsule on positive,negative,general and cognitive symptomes and prevention of metabolic syndrome in patients with schizophrenia on olanzapin treatment

Protocol summary

Summary

The objective of this study is to assess the efficacy and safety of administration of Crocin (from extract of *Crocus sativus*) for 12 week in patients with schizophrenia. This study will be undertaken in Razi Psychiatry Hospital, Tehran, Iran. Male patients with schizophrenia aged between 18-65, without prior history of metabolic syndrome or using any herbal treatment or special food diet will be treated with olanzapine 5-20 mg per day. After 4 to 6 weeks, in maintenance phase of treatment, they will be randomized to receive either Capsule of Crocin (30 mg/day) or placebo with the same shape beside olanzapin. The main efficacy measures are: change in BMI and Insulin Resistance, BPRS and MMSE Score. The Metabolic Syndrome will be evaluated in week 2, 6 and 12; while cognitive, positive, negative and general symptoms will be assessed in weeks 6 and 12 of the treatment, and the results will be compared to the baseline. ECG and complete blood test would be checked at baseline and in weeks 2, 6 and 12 for assessment of side effects. In addition, general satisfaction of treatment, changes in quality of sleep and changes in nicotine abuse of patients will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081912351N2**
Registration date: **2013-08-25, 1392/06/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-25, 1392/06/03

Registrant information

Name

Seiedeh Bentolhoda Mousavi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3340 1220

Email address

be.mousavi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation sciences Tarbiat Modares University

Expected recruitment start date

2013-06-05, 1392/03/15

Expected recruitment end date

2013-10-07, 1392/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of crocin capsule on positive,negative,general and cognitive symptomes and prevention of metabolic syndrome in patients with schizophrenia on olanzapin treatment

Public title

crocin and metabolic syndrome, general, positive, negative an cognitive symptomes in schizophrenic patients treated with olanzapin

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of schizophrenia according to DSM-IV-TR criteria; clinical stability without acute phase; no acute medical problem; no coronary heart disease or metabolic syndrome; no neurological disease; no substance abuse or dependency except nicotine; no usage of anti platelets drugs or ASA or herbal medicines; not being mental retarded; no special slimming or obesity diets
Exclusion criteria: Any unwanted side effects that interfere with standard treatment or cause patient refusal of treatment; Need to change olanzapine in the course of treatment for any reason

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

Street address

Koodakyar Ave, Daneshjoo Blvd, Evin

City

Tehran

Postal code

1985713834

Approval date

2013-06-05, 1392/03/15

Ethics committee reference number

2/8026/A/801/92

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Metabolic Syndrome Parameters (FBS, TGL, HDL, BP, Waist circumference)

Timepoint

weeks 0, 2, 6, 12

Method of measurement

Blood Sample Test and Physical Examination

Secondary outcomes

1

Description

Changes in Insuline Resistance, General, Positive and Negative and Cognitive Symptomes

Timepoint

Insuline Resistance: week 0 and 12, others weeks 0, 6 and 12

Method of measurement

HOMA-IR (Laboratory tests), BPRS, MMSE.

Intervention groups

1

Description

Intervention group: Olanzapin, 5 mg oral Tablets, 1 to 4 times per day for 4 months crocin (from extract of saffron), 15 mg oral Capsules, 2 times per day for 3 months

Category

Treatment - Drugs

2

Description

Control group: Olanzapin, 5 mg oral Tablets, 1 to 4 times per day for 4 months placebo, capsules with the same shape, 2 times per day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatry Hospital

Full name of responsible person

Dr. Farbod Fadai

Street address

Amin Abad St. Shahre Rey

City

Tehran

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding***empty***Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Dr. Farbod Fadai

Street address

Koodakyar Ave. Daneshjoo Blvd. Evin

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

University of Social Welfare and Rehabilitation Sciences

Proportion provided by this source**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***2****Sponsor****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Dr. S. Zahra Bathai

Street address

Jalale Ale Ahmad

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tarbiat Modares University

Proportion provided by this source**Public or private sector***empty***Domestic or foreign origin***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Dr. S. Bentolhoda Mousavi

Position

Psychiatry Resident

Other areas of specialty/work**Street address**

Koodakyar Ave, Daneshjoo Blvd, Evin

City

Tehran

Postal code

1985713834

Phone

+98 21 2218 0083

Fax**Email**

be.mousavi@uswr.ac.ir,b_mousavi@gmail.com

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

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Dr. Farbod Fadai

Position

Associated Professor of Psychiatry, Geriatric Fellowship

Other areas of specialty/work**Street address**

Koodakyar Ave, Daneshjoo Blvd, Evin

City

Tehran

Postal code

1985713834

Phone

+98 21 2218 0140

Fax**Email**

farbodfadai@uswr.ac.ir,farbodfadai@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Dr. S. Bentolhoda Mousavi

Position

Psychiatry Resident

Other areas of specialty/work

Street address

Koodakyar Ave. Daneshjo Blvd. Evin

City

Tehran

Postal code

Phone

00

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty