Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 recieve 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

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation sciencesTarbiat 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 accept 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 circumstance)
Timepoint
weeks0, 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 Resistence: 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

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
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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
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
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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
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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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