

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of Saffron Aqueous Extract and its active constitute crocin on prevention of metabolic syndrome in people with schizophrenia on olanzapin treatment

Protocol summary

Summary

The objective of this study is to assess the efficacy and safety of administration of Saffron aqueous extract (SAE) and its active constitute crocin for 12 week in patients with schizophrenia. This study will be undertaken in Razi Psychiatry Hospital, Tehran, Iran. Male inpatients 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 SAE (30 mg/day) or crocin (30 mg/day) or placebo with the same shape beside olanzapine. The main efficacy measures are: change in Metabolic Syndrome Criteria. The Metabolic Syndrome will be evaluated in week 6 and 12; Fasting blood glucose, serum lipids will be assessed at the baseline and will be repeated in weeks 2, 6 and 12. Waist circumference and blood pressure would be assessed at the baseline and will be repeated in weeks 6 and 12. Fasting blood level of insulin and HgbA1c would be measured at baseline and week 12. while complete blood test, TFT, RFT, LFT would be checked at baseline and in weeks 2, 6 and 12 for assessment of side effects. In addition, general satisfaction of treatment, and any unwanted side effects like GI disturbances or abnormal bleeding or hypersensitivity will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020312351N1**
Registration date: **2013-03-27, 1392/01/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-03-27, 1392/01/07

Registrant information

Name

Seiedeh Bentolhoda Mousavi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

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Iran (Islamic Republic of)

Phone

+98 21 3340 1220

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2013-03-05, 1391/12/15

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 Saffron Aqueous Extract and its active constitute crocin on prevention of metabolic syndrome in people with schizophrenia on olanzapin treatment

Public title

saffron and metabolic syndrome, general, positive, negative an cognitive symptoms in schizophrenic patients treated with olanzapin.

Purpose

Treatment

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

2012-12-24, 1391/10/04

Ethics committee reference number

25128 / 2 / 91/ 801 / 1

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 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 Symptoms

Timepoint

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

Method of measurement

HOMA-IR, BPRS, MMSE.

Intervention groups

1

Description

Intervention group 1: Olanzapin, 5 mg oral Tablets, 1 to 4 times per day for 4 mounts Aqua Extract of saffron, 15 mg oral Capsules,2 times per day for 3 mounts

Category

Treatment - Drugs

2

Description

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

Category

Treatment - Drugs

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

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

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
Added at 2013-08-19: Tarbiat Modares University
Full name of responsible person
Added at 2013-08-19: Dr.S.Zahra Bathai
Street address
Added at 2013-08-19: Jalale Ale Ahmad
City
Added at 2013-08-19: Tehran
Grant name
1392/5/28 پروژسسانی:
Grant code / Reference number
Added at 2013-08-19:
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Added at 2013-08-19: Tarbiat Modares University
Proportion provided by this source

Person responsible for general inquiries

Contact

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Person responsible for scientific inquiries

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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