

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Saffron (*Crocus sativus*) as an adjuvant therapy for the treatment of negative symptoms in patients with chronic schizophrenia : A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim

Investigating the effect of additive treatment of Saffron in patients with chronic schizophrenia

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

The study will be performed on patients with chronic schizophrenia attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of schizophrenia based on DSM-5 - The score less than 14 based on HARS - Age range: 18-60 years - At least, 4 months treated with Risperidone. Exclusion criteria: Diagnosis of another disorder in axis II - Diagnosis of a significant neurological or systemic disease, acute or chronic - History of central nervous system surgery - Treatment with ECT during the last 3 months.

Intervention groups

Intervention group: Patients treated with risperidone 4-6 mg per day + saffron capsule 15 mg twice per day for 8 weeks. Control group: Patients treated with risperidone 4-6 mg per day + placebo twice a day for 8 weeks.

Main outcome variables

Severity of schizophrenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N140**

Registration date: **2021-11-11, 1400/08/20**

Registration timing: **prospective**

Last update: **2021-11-11, 1400/08/20**

Update count: **0**

Registration date

2021-11-11, 1400/08/20

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Saffron (*Crocus sativus*) as an adjuvant therapy for the treatment of negative symptoms in patients with chronic schizophrenia : A randomized double blind and placebo controlled clinical trial

Public title

Saffron (*Crocus sativus*) as an adjuvant therapy for chronic schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of schizophrenia based on DSM-5 The score less than 14 based on HARS Age range: 18-60 years At least, 4 months treated with Risperidone

Exclusion criteria:

Diagnosis of another disorder in axis II Diagnosis of a significant neurological or systemic disease, acute or chronic History of central nervous system surgery Treatment with ECT during the last 3 months

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups). The best way to create randomization is to use random allocation. Random allocation in clinical trial studies refers to the process of randomly dividing participants into different groups. Randomization gives each participant an equal chance to participate in each group. Successful randomization requires that researchers and study participants be unable to predict the type of intervention received.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.TUMS.DDRI.REC.1400.040

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Severity of schizophrenia

Timepoint

Baseline and weeks 4 and 8

Method of measurement

By Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients treated with risperidone 4-6 mg (p.o) per day (Johnson & Johnson, Canada) + saffron capsule 15 mg (p.o.) twice per day (Institute of Medicinal Plants, ACECR, Karaj, Iran) for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients treated with risperidone 4-6 mg (p.o) per day (Johnson & Johnson, Canada) + placebo twice a day for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Dr. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street, Tehran

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

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msahrai@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2022 to 2027

To whom data/document is available

academic researchers

Under which criteria data/document could be used

users should cite the resource of data

From where data/document is obtainable

Prof Shahin Akhondzadeh

What processes are involved for a request to access data/document

by E mail

Comments