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)

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+98 21 5541 2222

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
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Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.
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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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Full name of responsible person
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Position
Professor of clinical psychopharmacology
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Other areas of specialty/work
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Person responsible for updating data

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Tehran University of Medical Sciences

Full name of responsible person
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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