Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Therapeutic effect of saffron extract on negative, positive and general symptoms of schizophrenia in comparison with placebo in patients with chronic schizophrenia

Protocol summary

Study aim

The aim of study was to evaluate the effect of saffron in patients with schizophrenia on positive, negative and general symptoms of patients.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 in 40 patients. Randomization using a random number table

Settings and conduct

In this study, 40 patients with schizophrenia were admitted to Golestan Salamat Center in Kerman Based on structured clinical interview (DSM-V TR), sampling is first available and then patients are divided into two groups, placebo and intervention. a random sequence is created from the table of random numbers and then even numbers are given to the intervention group and odd numbers to the control group. Two-way blinding, participants and researchers will not know about the distribution of saffron extract capsules and placebo. A sealed opaque envelope is used to hide drugs and placebo. The envelopes will be prepared by a non-research person The study period is four weeks and during this period, in addition to saffron capsules and placebo, they are routinely treated. Questionnaires of Positive and Negative Symptoms Scale, Hamilton Depression Scale and Hamilton Anxiety Scale are completed at the beginning and end of the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Age between 18 and 65 years, schizophrenia according to DSM-V-TR criteria. Exclusion criteria: General medical problems (coronary artery disease, metabolic syndrome and neurological diseases), substance abuse, use of anti-platelet and herbal medicines, allergy to saffron.

Intervention groups

Intervention group: Treated with 15 mg capsule of saffron extract twice a day Placebo group: placebo similar to the saffron capsule twice a day Both groups receive routine treatments.

Main outcome variables

Negative Symptoms , Positive Symptoms and General Symptoms of Schizophrenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210525051404N1**
Registration date: **2021-08-10, 1400/05/19**
Registration timing: **prospective**

Last update: **2021-08-10, 1400/05/19**
Update count: **0**

Registration date

2021-08-10, 1400/05/19

Registrant information

Name

Mahdi Hajirezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 0409

Email address

mahdi.hajirezaei43@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Therapeutic effect of saffron extract on negative, positive and general symptoms of schizophrenia in comparison with placebo in patients with chronic schizophrenia

Public title
Therapeutic effect of saffron extract in patients with chronic schizophrenia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Schizophrenia according to the DSM-V-TR criteria stable symptoms Age between 18 and 65 years
Exclusion criteria:
General medical problems (including coronary artery disease, metabolic syndrome, and neurological diseases) Drug abuse Taking antiplatelet drugs Taking herbal medicines Sensitivity to saffron
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, sampling is available first and then eligible patients will be assigned to two groups by simple random sampling. For this purpose, first a random sequence will be created from the table of random numbers. Then the extracted even numbers will be assigned to the intervention group and the odd numbers will be assigned to the control group. This process will continue to reach the sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding is two-way blind so that the participants and the research physician will not be aware of the distribution of saffron and placebo extract capsules, which are similar in color, size, shape and smell to the main drug. To hide the drugs and placebo, they will be placed in a sealed matte envelope numbered in a row. Envelopes will be prepared by a non-research person
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman university of medical science
Street address
Shahid beheshti Hospital, Jomhori Blv
City
Kerman
Province
Kerman
Postal code
7618833639
Approval date
2021-05-23, 1400/03/02
Ethics committee reference number
IR.KMU.AH.REC.1400.036

Health conditions studied

1

Description of health condition studied
schizophernia
ICD-10 code
F20
ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
Negative symptoms of schizophernia
Timepoint
Beginning of research and end of research (fourth week)
Method of measurement
Positive and Negative Syndrome Scale

2

Description
Positive symptoms of schizophrenia
Timepoint
Beginning of research and end of research (fourth week)
Method of measurement
Positive and Negative Syndrome Scale

3

Description

General symptoms of schizophrenia

Timepoint

Beginning of research and end of research (fourth week)

Method of measurement

Positive and Negative Syndrome Scale

Secondary outcomes

1

Description

Symptoms of anxiety

Timepoint

Beginning of research and end of research (fourth week)

Method of measurement

Hamilton Anxiety Scale

2

Description

Symptoms of depression

Timepoint

Beginning of research and end of research (fourth week)

Method of measurement

Hamilton Depression Scale

Intervention groups

1

Description

Intervention group: Treated with 15 mg capsule of saffron extract twice a day with routine treatments

Category

Treatment - Drugs

2

Description

Control group: Placebo is prepared in the form of a capsule that is similar to the saffron capsule in terms of shape, weight and color, and two tablets are prescribed daily. In addition, routine treatments are performed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Health Center

Full name of responsible person

Ghediseh Bani vaheb

Street address

Haft Bagh Alavi

City

kerman

Province

Kerman

Postal code

7635119895

Phone

+98 34 3322 0902

Email

golestan.salamat@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

Somayeh Crossroads

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3815

Email

VCR@KMU.AC.IR

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mahdi Haji Rezaei

Position

Resident of psychiatry

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

Street address

Shahid Beheshti Hospital, Jomhuri Blvd, Kerman, Iran

City

kerman

Province
Kerman

Postal code
7618833639

Phone
+98 34 3211 0409

Email
mahdi_hajirezaei@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Nabi Banna Zadeh Mahani

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Shahid Beheshti Hospital, Jomhuri Blvd, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7618833639

Phone
+98 34 3211 0409

Email
n_banazadeh@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Mahdi Haji Rezaei

Position
Resident of Psychiatry

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Shahid Beheshti Hospital, Jomhuri Blvd, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7618833639

Phone
+98 34 3211 0409

Email
mahdi_hajirezaei@yahoo.com

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
Yes - There is a plan to make this available

Title and more details about the data/document
At the end of the study, some information including the effect of saffron medicine in the treatment of schizophrenia symptoms, after identifying individuals, will be shared with health enthusiasts.

When the data will become available and for how long
2 months after data analysis

To whom data/document is available
Health researchers

Under which criteria data/document could be used
In order to use the results and during the written request

From where data/document is obtainable
Mahdi Haji Rezaei- Email

What processes are involved for a request to access data/document
The purpose of accessing data - requesting e-mail

Comments