

# 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**

schizophrenia

**ICD-10 code**

F20

**ICD-10 code description**

Schizophrenia

**Primary outcomes****1****Description**

Negative symptoms of schizophrenia

**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

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Haft Bagh Alavi

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr Abbas Pardakhti

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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**

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

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Shahid Beheshti Hospital, Jomhuri Blvd, Kerman, Iran

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Nabi Banna Zadeh Mahani  
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Associate professor  
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Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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Mahdi Haji Rezaei  
**Position**  
Resident of Psychiatry  
**Latest degree**  
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### Other areas of specialty/work

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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

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