

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of berberine alkaloid on positive and negative symptoms in patients with schizophrenia: a randomized placebo-controlled double-blind clinical trial

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of Berberine on improving the symptoms of patients with Schizophrenia

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients. NCSS (Number Cruncher statistical system) software and block random method are used to randomize the study

##### Settings and conduct

60 patients with schizophrenia who referred to Ibn Sina Psychiatric Hospital in Shiraz in 2020-21 will be included in the study. These people will then be randomly divided into groups receiving placebo and berberine.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: schizophrenia; taking antipsychotic medication in the last three months. Exclusion criteria: having concomitant psychiatric illness; pregnancy or lactation; simultaneous receiving of ECT.

##### Intervention groups

Intervention group: patients receive 2 to 6 mg of risperidone daily with a berberine capsule. Placebo group: patients receive 2 to 6 mg of risperidone daily with one placebo capsule.

##### Main outcome variables

Change in PANSS questionnaire score (positive and negative symptom scale)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190726044339N1**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

##### Registration date

2020-12-12, 1399/09/22

##### Registrant information

###### Name

Seyed Hamdollah Mosavat

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3725 4105

###### Email address

hamdi\_88114@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-05, 1399/09/15

##### Expected recruitment end date

2021-03-19, 1399/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of berberine alkaloid on positive and negative symptoms in patients with schizophrenia: a randomized placebo-controlled double-blind clinical trial

##### Public title

The effect of berberine on the symptoms of patients with schizophrenia

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Having schizophrenia Received antipsychotic medication in the last three months

### **Exclusion criteria:**

Having other psychiatric disorder Pregnancy and lactation Receive concomitant ECT

## **Age**

No age limit

## **Gender**

Both

## **Phase**

2-3

## **Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

## **Sample size**

Target sample size: **60**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

The researcher will enrolled participants based on convenience sampling method. NCSS software (Number Cruncher Statistical System) and block randomization method will use for randomization the study. In the block randomization method, participants will categorize into 6 blocks (AABB, ABAB, BBAA, BABA, ABBA, BAAB), each block containing 4 participants. In this study, "A" will assign to the drug group and "B" to the placebo group, for example: in the "ABAB" block, the first person entered the drug group, the second person entered the placebo group, the third person entered the drug group, and the fourth person entered the placebo group. Thus, all eligible participants will randomly assigned to one of the study arms according to the randomization list.

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

Physicians, patients, and drug deliverer will blind to the allocation of intervention. It should be noted that the drugs' containers is the same. Additionally, placebo capsule is similar to berberine capsule regarding the color and shape

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

**Ethics committee**

## **Name of ethics committee**

Shiraz University of Medical Sciences

## **Street address**

Ibn Sina Hospital; Hafez street

## **City**

Shiraz

## **Province**

Fars

## **Postal code**

7134845794

## **Approval date**

2018-05-01, 1397/02/11

## **Ethics committee reference number**

IR.SUMS.MED.REC.1399.371

## **Health conditions studied**

### 1

## **Description of health condition studied**

Schizophrenia

## **ICD-10 code**

F20

## **ICD-10 code description**

Schizophrenia

## **Primary outcomes**

### 1

## **Description**

Change in PANSS questionnaire score (positive and negative symptom scale)

## **Timepoint**

One month

## **Method of measurement**

PANSS( positive and negative symptom scale)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

## **Description**

Intervention group: Risperon 2 to 6 mg daily with one berberine capsule daily for a month

## **Category**

Treatment - Drugs

### 2

## **Description**

Control group: Risperon 2 to 6 mg daily with one placebo capsule daily for a month

## **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Ibn Sina Psychiatric Hospital(Shiraz)  
**Full name of responsible person**  
Dr. Ebrahim Moghimi Sarani  
**Street address**  
Hafez street  
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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Shiraz University of Medical Sciences  
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Dr. Ebrahim Moghimi Sarani  
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moghimiebrahim@yahoo.com  
**Grant name**  
Vice Chancellor for Research, Shiraz University of Medical Sciences  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shiraz 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**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Ghorban Nejad  
**Position**  
Resident  
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Medical doctor  
**Other areas of specialty/work**  
Psychiatrics  
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## Person responsible for scientific inquiries

### Contact

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Seyed Hamdollah Mosavat  
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Resident  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Seyed Hamdollah Mosavat

**Position**

Resident

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychiatrics

**Street address**

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**Province**

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**Postal code**

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**Phone**

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available