Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 2020-21will 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
Intrvention 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)

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+98 71 3725 4105

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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 beriberine 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: Risperson 2 to 6 mg daily with one berberine capsule daily for a month

Category

Treatment - Drugs

2

Description

Control group: Risperson 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

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Hafez street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

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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