

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of risperidone efficacy versus placebo in treatment of obsessive compulsive disorder symptoms in bipolar patients

Protocol summary

Study aim

Evaluation the efficacy of resperidon to deminish obsession symptoms in bipolar patients

Design

This clinical trial has a control group, it has parallel, double-blind, phase 3, randomized groups, which is conducted on two groups of 20 patients. Both groups received standard treatment, and the case group received risperidone and the control group received placebo

Settings and conduct

Among the admitted patients and patients referred to the Ebnesina psychiatric clinic in Shiraz who are simultaneously suffering from bipolar disorder and obsessive compulsive disorder and have passed the acute stage of bipolar depression or mania and are in a stable condition, the selected patients received the desired drug and placebo. They are checked at the mentioned intervals of 4, 8 and 12 weeks. The packaging of the drugs and placebo was done by a third person other than the researcher and the evaluator of the results

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-suffering from bipolar disorder type 1 or 2 ; 2-coincidence of bipolar disorder and obsessive compulsive disorder; 3-Literacy for reading and writing; 4-Absence of extrapyramidal movement disorders; 5-consent for entering study Exclusion criteria: Acute phase of mania or depression ;Major medical conditions(cardiovascular-respiratory-renal-digestive) ;Pregnancy

Intervention groups

in case group containing 20 patients, risperidone is administered for 3 months and patients are checked for obsession symptoms based on Yale-Brown questioner after 4, 8 and 12 weeks post treatment. in control group placebo is administered instead of risperidone. both groups receive standard treatment containing Li and benzodiazepine if needed.

Main outcome variables

Obsessional symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140926019295N3**

Registration date: **2022-09-13, 1401/06/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-13, 1401/06/22**

Update count: **0**

Registration date

2022-09-13, 1401/06/22

Registrant information

Name

Ali Sahraian

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 9319

Email address

sahraian@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of risperidone efficacy versus placebo in treatment of obsessive compulsive disorder symptoms in bipolar patients

Public title
Evaluation of risperidone efficacy versus placebo in treatment of obsessive compulsive disorder symptoms in bipolar patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 DSM-5 criteria for Bipolar disorder type 1 or 2 yale-brown score higher than 61 Coincidence of Bipolar disorder and obsessive-compulsive disorder
Exclusion criteria:
 Acute phase of mania or depression Major medical conditions(cardiovascular-respiratory-renal-digestive) Pregnancy

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method in this study will be permutation block method in such a way that A represents the person who receives the intervention and B represents the person who receives the control. This method considering blocks of four so that the total number of possible permutations of four is equal to 6, including: ABAB, BABA, AABB, BBAA and BAAB ABBA. Then, by using the table of random numbers and assigning a code from 0 to 9 to each of the permutations, the desired random list of 40 items that includes 10 blocks of 4 items (total number of samples = 40 x 10) is produced (using from the computer) and the order of assigning each of the methods to each of the samples participating in the study is determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the patients and the evaluator who perform the Yale-Brown test to measure the severity of obsessive-compulsive symptoms are not aware of the

grouping and the type of medication received (risperidone versus placebo).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Shiraz University of Medical Sciences
Street address
 chamran Blvd. hafez hospital. psychiatry department
City
 shiraz
Province
 Fars
Postal code
 7144714189
Approval date
 2022-05-10, 1401/02/20
Ethics committee reference number
 IR.SUMS.REC.1401.113

Health conditions studied

1

Description of health condition studied
اختلال وسواسی جبری-اختلال دوقطبی

ICD-10 code
F42

ICD-10 code description
Obsessive-compulsive disorder

Primary outcomes

1

Description
Obsessional symptoms

Timepoint
4 and 8 weeks after receiving risperidone

Method of measurement
yale brown questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: risperidone with initial dose 5mg for 12 weeks and at intervals of 4, 8, and 12 weeks, the level of obsessive symptoms will be evaluated using the Yale Brown questionnaire

Category

Treatment - Drugs

2

Description

Control group: In the control group, like the intervention group, they receive standard treatment including lithium and benzodiazepine, and they are also given a placebo drug.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebne sina clinic

Full name of responsible person

ali sahraian

Street address

Hafez st. Ebne sina hospital

City

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7144734189

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+98 71 3228 9604

Email

mghavipisheh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mahtab Memarpour

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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

Shiraz University of Medical Sciences

Proportion provided by this source

50

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

Mahsa Ghavipisheh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

professor

Latest degree

Subspecialist

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Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahsa Ghavipisheh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information is provided

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

No - There is not 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