

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of the effect of bipolar disorder treatment (Lithium+Olanzapin+Clonazepam) and placebo with Riluzole-containing regimen in controlling obsessive symptoms of bipolar patients

Protocol summary

Study aim

Determining the effect of treatment of bipolar disorder and placebo in controlling the symptoms of obsession
Determining the effect of treating bipolar disorder in addition to riluzole in bipolar disorder
Announcing the results to activists and therapists in the field of mental health in better control of obsessive symptoms in patients with BMD

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, on 40 patients.

Settings and conduct

Each group will consist of 20 people, one group will be given lithium, olanzapine, clonazepam and riluzole for 16 weeks, and the other group will be given lithium, olanzapine, clonazepam and placebo. Hiding is done using software. Participants do not know which group they are in. The data analyzer does not know which group it is analyzing. The number of people in the intervention and control groups is the same. The number of weeks of drug use is the same, so the patient is blind to the type of treatment. Place:Ostad Mohrari Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria Having DSM 5 criteria for bipolar disorder
Having a score higher than 18 in the Y_BOCS test
Exclusion criteria pregnancy addiction medical problems

Intervention groups

Each group will consist of 20 people, one group will be given lithium, olanzapine, clonazepam and riluzole for 16 weeks, and the other group will be given lithium, olanzapine, clonazepam and placebo. The evaluation of the intensity of obsessive symptoms in zero week is done by the project manager with the presence and training of the main collaborator with the questionnaire (Y-BOCS) and obsessive symptom changes based on Y-BOCS in 4th, 8th, 12th and 16th weeks .

Main outcome variables

Score obtained in the Y-BOCS questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211118053093N4**

Registration date: **2022-08-19, 1401/05/28**

Registration timing: **prospective**

Last update: **2022-08-19, 1401/05/28**

Update count: **0**

Registration date

2022-08-19, 1401/05/28

Registrant information

Name

Kimia Sahraian

Name of organization / entity

Eghlid Higher Education Center

Country

Iran (Islamic Republic of)

Phone

+98 71 3630 3886

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leilarazeghian1366@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-22, 1401/05/31

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of bipolar disorder treatment (Lithium+Olanzapin+Clonazepam) and placebo with Riluzole-containing regimen in controlling obsessive symptoms of bipolar patients

Public title

Riluzole in the control of obsession in bipolar patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having DSM 5 criteria for bipolar disorder Having a score higher than 18 in the Y_BOCS test

Exclusion criteria:

Pregnancy Addiction Medical problems

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Participants do not know which group they are in. The data analyser does not know which group it is analysing. The number of weeks of drug use is the same, so the patient is blinded to the type of treatment. Data analysis is given only data and does not know what treatment was done for witch group

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

Kilometer 13 of Shiraz-Isfahan highway, Ostad Moharreri Hospital

City

Shiraz

Province

Fars

Postal code

71441-13331

Approval date

2022-07-05, 1401/04/14

Ethics committee reference number

IR.SUMS.MED.REC.1401.191

Health conditions studied**1****Description of health condition studied**

BMD

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

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

Yale Brown Obsessive-Compulsive Scale score

Timepoint

week 0and4and8and12and16

Method of measurement

Yale Brown Obsessive-Compulsive Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: It includes 20 patients who receive riluzole in addition to the main drugs, and in weeks 0, 4, 8, 12, and 16, they must complete the Yale Brown Obsessive Compulsive Scale questionnaire.

Category

Treatment - Drugs

2**Description**

Control group: It includes 20 patients who receive a

placebo in addition to the main drugs. And in weeks 0, 4, 8, 12, and 16, they must complete the Yale Brown Obsessive Compulsive Scale questionnaire.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ostad Mohrari Hospital

Full name of responsible person

Leila RazeghianJahromi

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13 km Shiraz-Isfahan, Ostad Mehrari Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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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

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

Leila Razeghian Jahromi

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact**

Name of organization / entity

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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