Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Aripiprazole as an adjuvant treatment for obsessive and compulsive symptoms in bipolar disorder: A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

Investigating the effect of adding aripiprazole as adjunctive therapy in the treatment of obsessive-compulsive symptoms in patients with bipolar disorder

Design

This double-blind clinical trial study has a parallel control group, where the patient and the researcher do not know the type of drug received. 23 patients are allocated in each group. Randomization will be done using a table of random numbers.

Settings and conduct

This study is a double-blind clinical trial in which the patient and the researcher do not know the type of drug received This study will be conducted on all qualified patients under treatment referring to Golestan Hospital in the period of 2021-2022

Participants/Inclusion and exclusion criteria

Included criteria: age 18 to 60 years, confirmation of bipolar disorder based on DSM-5 criteria. Exclusion criteria: not having cardiovascular, respiratory, kidney or digestive diseases; Not pregnant, not suffering from drug or alcohol abuse

Intervention groups

Intervention group: They will receive quetiapine with the addition of sodium valproate and aripiprazole. Aripiprazole will be added to the patients' current medications with an initial dose of 5 mg per day, and then the dose will be increased by 5 mg per week to 20 mg per day. The dose of aripiprazole will be adjusted based on the patient's response or patient tolerance. The effect of the drug will be evaluated in weeks 4, 8 and 12. Control group: they will receive quetiapine plus sodium valproate and will be evaluated in weeks 8 and 12.

Main outcome variables

Severity of obsession, severity of depression, severity of mania

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230814059145N1**
Registration date: **2023-10-22, 1402/07/30**
Registration timing: **prospective**

Last update: **2023-10-22, 1402/07/30**
Update count: **0**

Registration date

2023-10-22, 1402/07/30

Registrant information

Name

Rakhshan Abiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4428 6943

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-01, 1402/08/10

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Aripiprazole as an adjuvant treatment for obsessive and compulsive symptoms in bipolar disorder: A randomized, double-blind, placebo-controlled clinical trial

Public title
Aripiprazole as an adjuvant treatment for obsessive and compulsive symptoms in bipolar disorder

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 60 years Confirmation of bipolar disorder based on DSM-5 criteria
Exclusion criteria:
Not having cardiovascular, respiratory, kidney or digestive diseases Not pregnant Not suffering from drug or alcohol abuse

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of randomization is the use of random numbers that are used from random sequence generation software, which refers to the method used to perform a random sequence on the participants in the study, in such a way that before allocating the individual, the allocation group The finding is not clear. By using sealed opaque mail envelopes with a random sequence, each of the generated random sequences is recorded on a card and the cards are placed inside the mail envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients are randomly divided into two control and intervention groups, the control group receives placebo in addition to the drugs consumed, and the intervention group receives aripiprazole in addition to the drugs consumed, and the main partner of the project and the patient remain unaware of the type of treatment.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz, Golestan St., Farvardin Blvd., Jundishapur University of Medical Sciences, Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2022-11-01, 1401/08/10

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.116

Health conditions studied

1

Description of health condition studied
Bipolar disorder

ICD-10 code
F31

ICD-10 code description
Bipolar disorder

Primary outcomes

1

Description
Depression

Timepoint
Before the intervention and weeks 4, 8 and 12 after the intervention

Method of measurement
Hamilton

2

Description
Symptoms of mania

Timepoint
Before the intervention and weeks 4, 8 and 12 after the intervention

Method of measurement
Young mania rating scale

3

Description
Obsessive compulsive symptoms
Timepoint
Before the intervention and weeks 4, 8 and 12 after the intervention
Method of measurement
Yale brown obsessive compulsive scale scoring

Secondary outcomes

1

Description
Drug complication
Timepoint
Before the intervention and weeks 4, 8 and 12 after the intervention
Method of measurement
Abnormal Involuntary Movement scale

Intervention groups

1

Description
Intervention group:The intervention group will receive quetiapine with the addition of sodium valproate and aripiprazole. Aripiprazole will be added to patients' current medications at an initial dose of 5 mg per day, and then the dose will be increased by 5 mg per week up to 20 mg per day.Aripiprazole is produced by Actoverco pharmaceutical company.
Category
Treatment - Drugs

2

Description
Control group: they will receive quetiapine plus sodium valproate and placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Hamzeh rostami
Street address
Golestan hospital, Golestan street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Ahvaz Jundishapur University of Medical Sciences, Farvardin Blvd, Golestan Ave, Ahvaz Ahvaz
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Maryam Poorshams
Position
Associate professor
Latest degree
Specialist
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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available