

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Assessing the effectiveness of treatment by aripiprazole and placebo with lithium and benzodiazepin to control of obsesion in patients with Bipolar mood disorder

Protocol summary

Summary

Study design: Interventional clinical trial and double blind. The purpose of the study: compared the effect of aripiprazole with placebo on the obsessive-compulsive symptoms in patients with bipolar mood disorder. Common treatment for this disorder contain mood stabilization preferably Lithium plus Antipsychotic and Benzodiazepines. Obsessive Compulsive Disorder (OCD) is the most common comorbidities associated with bipolar disorder that can worsen prognosis and increase risk of suicide. Selective Serotonin Reuptake Inhibitor and Tricyclic antidepressant are common treatment of OCD but this drugs with probability of shift to mania. Aripiprazole is effective on mania and mixed episode and also relapse prevention. Main inclusion and exclusion criteria: is Yale Brown Score more than 16 at baseline. Population: Patients that referred to Shiraz University of Medical Science clinics are target. Target size: is 40, 20 patients in each group (A and B). Intervention: Aripiprazole start with initial dose of 5 milligram/day and 5 milligram added every week till reach up to 20 mg daily. One group receive Aripiprazole in addition to Lithium and Benzodiazepine and another receive placebo in addition to Lithium and Benzodiazepine. Variable: Obsession severity assessment done at week 0, 4th and 8th. Side effects will be evaluated according to the side effects list at weeks 4 and 8.

General information

Acronym

Research center for Psychiatry and Behavior Science

IRCT registration information

IRCT registration number: **IRCT2014092719295N1**

Registration date: **2017-03-07, 1395/12/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-07, 1395/12/17

Registrant information

Name

Ali Sahraian

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research Shiraz University of Medical Sciences

Expected recruitment start date

2016-05-14, 1395/02/25

Expected recruitment end date

2017-03-15, 1395/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of treatment by aripiprazole and placebo with lithium and benzodiazepin to control of obsesion in patients with Bipolar mood disorder

Public title

Assessing the effectiveness of treatment by aripiprazole and placebo for control of obsession in patients with Bipolar mood disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with a diagnosis of bipolar disorder according to the DSM IV TR criteria; Yale Brown Score more than 16 at baseline; No important medical condition
Exclusion criteria: Patients were not in acute phase of depression and mania; Important medical condition (cardiovascular, Respirator, renal, Gastrointestinal disease); Pregnancy; Yale Brown Score less than 16 at baseline

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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

zand avenue, medical school

City

Shiraz

Postal code

Approval date

2016-05-14, 1395/02/25

Ethics committee reference number

IR.SUMS.MED.REC.1395.16

Health conditions studied

1

Description of health condition studied

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

2

Description of health condition studied

Obsessive-Compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Obsession severity

Timepoint

Weeks 0 and 4 and 8

Method of measurement

Yale Brown Test (Y-BOCS)

Secondary outcomes

1

Description

Side edffect

Timepoint

Weeks 4 and 8

Method of measurement

Side effect list

Intervention groups

1

Description

The study is a double blind clinical trial. Interventional Group (Group A) is 20 people that receive Aripiprazole in addition to Lithium and Benzodiazepine (if necessary). Administrator is doing Obsession severity assessment at week 0 by Yale Brown questionnaire and main partner do follow in next weeks. Side effects will be evaluated according to the side effects list at weeks 4 and 8. Change in symptoms of obsession also evaluated at weeks 4 and 8. Administrator is present every tuesday to visit patients at the clinic and give number to patient if necessary. Lithium and Benzodiazepine dose prescribed at a level which will control symptoms. Aripiperazol start with initial dose of 5 milligram/day and 5 milligram added every week till reach up to 20 mg daily (Base on tolerance drugs be adjusted). Yale Brown questionnaire has 10 items and each item receives a score of 0 to 4 (no symptoms to maximum). Questions are about time for

washing, create problems in life, patient resistance and control on thoughts and rituals. The same questions ask about compulsions. The questionnaire had Validity and reliability in various studies.

Category

Treatment - Drugs

2

Description

This study is a double blind clinical trial. Control Group (Group B) is 20 people that receive Placebo in addition to Lithium and Benzodiazepine (if necessary). Administrator is doing obsession severity assessment at week 0 by Yale Brown questionnaire and main partner do follow in next weeks. Side effects will be evaluated according to the side effects list at weeks 4 and 8. Change in symptoms of obsession also evaluated at weeks 4 and 8. Administrator is present every tuesday to visit patients at the clinic and give number to patient if necessary. Lithium and Benzodiazepine dose prescribed at a level which will control symptoms (drugs Will be adjusted based on patient tolerance). Placebo administered with the same dose of Aripiprazol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Zahra Ehsaei

Street address

Zand avenue

City

Shiraz

2

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Zahra Ehsaei

Street address

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3

Recruitment center

Name of recruitment center

Ebnsina Hospital

Full name of responsible person

Zahra Ehsaei

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Hafezie avenue

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research Shiraz University of Medical Sciences

Full name of responsible person

Ebrahim Moghimi

Street address

Zand street, Shiraz University of Medical Sciences

City

Shiraz,

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for Research Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Psychiatry, Shiraz University of Medical Sciences

Full name of responsible person

Zahra Ehsaei

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty