Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Shiraz University of Medical Sciences
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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 obsesion 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 Arippiperazol.

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

Chamran avenue

City

Shiraz

3

Recruitment center

Name of recruitment center

Ebnsina Hospital

Full name of responsible person

Zahra Ehsaei

Street address

Hafezie avenue

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellery 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 chancellery 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, Siraz University of Medical Sciences

Full name of responsible person

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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