

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3627 9319

###### Email address

sahraian@sums.ac.ir

##### 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 Aripiperazol.

#### 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 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

##### Position

Psychiatry Resident

##### Other areas of specialty/work

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## Person responsible for scientific

## **inquiries**

### **Contact**

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Psychiatrist, Professor

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## **Person responsible for updating data**

### **Contact**

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**Other areas of specialty/work**

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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*