

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Aripiprazol as an adjuvant on obsessive compulsive symptoms in patients with Schizophrenia - A randomized placebo-controlled study

#### Protocol summary

##### Study aim

Schizophrenia and obsessive-compulsive disorder are considered as two distinct disorders with high rates of comorbidity, so that the incidence of clinically significant obsessive compulsive symptoms in patients with schizophrenia is between 10% and 59%. It has been known for more than a century that these two disorders are comorbid, But the results of studies about this association and its impact on the clinical symptoms have been controversial. The aim of this study was to evaluate the efficacy and safety of aripiprazole in the treatment of obsessive-compulsive symptoms in patients with schizophrenia.

##### Design

Clinical trial with control group, with parallel groups, double blind, randomized.

##### Settings and conduct

After sampling, patients are divided into two groups by block method. In the intervention group, Aripiprazole and in the control group placebo was given.

##### Participants/Inclusion and exclusion criteria

Women and men admitted to the psychiatric wards of the Zare hospital in Sari, who were between the ages of 18 and 65, diagnosed with schizophrenia simultaneously had obsessive-compulsive symptoms. If they received psychotropic drugs, dosage was fixed one month before and during the study. Patients with psychiatric disorders in the first axis, substance dependency, patients undergoing ECT treatment in the last six months, people with mental retardation, pregnant or lactating women, people with uncontrolled underlying conditions, patients who were treated with aripiprazole, and patients with a history of allergy or intolerance to aripiprazole were excluded from the study.

##### Intervention groups

In the intervention group, aripiprazole tablet was started at a dose of 5 mg per day and increased to 20 mg. In the control group, patients received placebo tablets that were similar in shape and color to the aripiprazole tablet.

#### Main outcome variables

Obsessive-compulsive symptoms in patients.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181001041192N1**

Registration date: **2018-12-16, 1397/09/25**

Registration timing: **retrospective**

Last update: **2018-12-16, 1397/09/25**

Update count: **0**

##### Registration date

2018-12-16, 1397/09/25

##### Registrant information

##### Name

Ideh Ghafour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3321 0315

##### Email address

ideh.bhn@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-07, 1397/07/15

##### Expected recruitment end date

2018-12-06, 1397/09/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Aripiprazol as an adjuvant on obsessive compulsive symptoms in patients with Schizophrenia – A randomized placebo-controlled study

**Public title**

The effect of Aripiprazole on obsessive compulsive symptoms

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women and men admitted to the psychiatric wards of the Zare hospital in Sari, who were between the ages of 18 and 65. Patients diagnosed with schizophrenia based on DSM-5 criteria that simultaneously had obsessive-compulsive symptoms. If they received medications such as mood-stabilizers and anti-depressant medications along with their antipsychotic regimen, their dosage was fixed one month before the study began and during the study.

**Exclusion criteria:**

The presence of psychiatric disorders in the first axis, as bipolar disorder or major depressive disorder. Substance dependency (based on DSM-5, as well as 6-month relapse or substance abuse in the three months prior to the onset of the study or positive urine specimen testing at the start of the study). Patients treated with ECT in the last six months. Individuals with suicidal/homicidal ideas or attempts at the start of the study or 6 months before the start of the study. People with intellectual disabilities. Pregnant or lactating women. Patients with neurological disorders such as dementia, delirium, uncontrolled seizure and head trauma. People with uncontrolled underlying conditions such as cardiovascular disease, liver and kidney failure, various malignancies, endocrine disorders and hematological disorders. Patients who have already been treated with aripiprazole. Patients who had a history of allergy or intolerance to aripiprazole.

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples were gradually introduced over time. Blocking was started by sampling, and individuals were classified in those blocks according to the features defined for the

characteristics of each block, due to their homogeneity. The subjects were matched for age, sex, and diagnosis. After completing the sampling, they were divided into two groups by block method. Initially the block size was selected. In order to be blinded by the person who performed the sampling, the size of the block was not mentioned. All possible blocks were assigned according to the layout of the individuals in each possible group, and each block was assigned a number. Then the number of blocks was selected from the random numbers table. Individuals were assigned to each of the intervention or control groups, respectively.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants as well as clinical caregivers were blinded to the drug given to the patient.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Mazandaran University of Medical Sciences

**Street address**

Jouybar road, Sari.

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815733971

**Approval date**

2017-09-27, 1396/07/05

**Ethics committee reference number**

IR.MAZUMS.REC.95.2505

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

Obsessive-compulsive symptoms in patients with schizophrenia

**ICD-10 code**

F20

**ICD-10 code description**

Schizophrenia

**Primary outcomes**

## 1

### **Description**

Obsessive-compulsive symptoms in patients with schizophrenia.

### **Timepoint**

The beginning of the study and the end of the fourth and sixth weeks.

### **Method of measurement**

by the Yale-Brown Obsessive Scale (Y-BOCS).

## **Secondary outcomes**

## 1

### **Description**

Global Assessment of Functioning

### **Timepoint**

At the beginning of the study, the end of the fourth and sixth weeks

### **Method of measurement**

Global Assessment of Functioning Scale (GAF)

## 2

### **Description**

Positive and negative and general Symptoms

### **Timepoint**

At the beginning of the study, the end of the fourth and sixth weeks

### **Method of measurement**

Positive and Negative Syndrome Scale (PANSS)

## 3

### **Description**

Assess extrapyramidal side effects

### **Timepoint**

Weekly

### **Method of measurement**

Abnormal Involuntary Movement Scale(AIMS), Barnes Akathisia Rating Scale (BARS), Simpson-Angus Scale (SAS).

## **Intervention groups**

## 1

### **Description**

In the intervention group, in addition to prescriptive antipsychotics, aripiprazole tablet was started at a dose of 5 mg per day. The dose of aripiprazole was increased to 10 mg on the second day, on the third day to 15 mg, and on the fourth day to 20 mg, and continued until the end of the study with the same dose.

### **Category**

Treatment - Drugs

## 2

### **Description**

In the control group, in addition to the antipsychotic treatment administered, placebo tablets, which were

similar in shape and color to the aripiprazole pill, were prepared and used such as the dosage given in the aripiprazole group.

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Zare Hospital

#### **Full name of responsible person**

Ideh Ghafour

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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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### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Mazandaran 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**  
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Mazandaran University of medical sciences  
**Full name of responsible person**  
Dr Abbas Massoudzadeh  
**Position**  
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Yes - There is a plan to make this available  
**Study Protocol**  
Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Not applicable  
**Informed Consent Form**  
No - There is not a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Not applicable  
**Data Dictionary**  
Not applicable  
**Title and more details about the data/document**  
Participant data file is publicly available because the information is filled in the questionnaire. The protocol for studying and reporting clinical studies is also available.  
**When the data will become available and for how long**  
The access period: 3 months after printing the results.  
**To whom data/document is available**  
Researchers working at academic institutions.  
**Under which criteria data/document could be used**  
Contact the authors by email.  
**From where data/document is obtainable**  
Contact the authors by email.  
**What processes are involved for a request to access data/document**  
Contact the authors by email.  
**Comments**