

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)

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Email address

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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

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Jouybar road, Sari.

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

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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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