Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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

Name of organization / entity

Mazandaran University of medical sciences

Full name of responsible person

Dr Abbas Massoudzadeh

Position

Professor

Latest degree

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Other areas of specialty/work

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Ideh Ghafour

Position

Resident

Latest degree

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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