

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of the Effectiveness of Aripiprazole and Risperidone in Improving Obsessive-compulsive symptoms in Bipolar patients Comorbid Obsessive-compulsive disorder

Protocol summary

Study aim

Comparison of the efficacy of Aripiprazole and Risperidone in the treatment of Obsessive-Compulsive Symptoms in Bipolar patients with Obsessive-Compulsive Disorder

Design

In this study, 60 patients with Bipolar Disorder with Obsessive-Compulsive Disorder are enrolled on the basis of DSM-5 criteria. The companies are randomly divided into two groups and each participant is assigned a code.

Settings and conduct

60 eligible patients with Bipolar Disorder with comorbid Obsessive-Compulsive Disorder and referred to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Participants/Inclusion and exclusion criteria

Inclusion Criteria are definitive diagnosis of Bipolar Disorder with Obsessive-Compulsive Disorder based on DSM-5 criteria, Age 18 to 65 years and Exclusion Criteria are acute and severe physical illness during study, Substance abuse and alcohol abuse in the six months before study, Accompanied with other psychiatric disorders.

Intervention groups

The first group is given a dose of 2.5 mg of Aripiprazole and is gradually increased every 5 days 2.5 mg daily for up to 10 mg per day for 15 days and continues for up to 12 weeks. The second group starts the 1-mg dose of Risperidone and gradually releases to the end of the second week at a dose of 4 mg per day and lasts for up to 12 weeks.

Main outcome variables

Comparison of the mean score of Y-BOCS in the group receiving Aripiprazole at the beginning and end of study. Comparison of the mean score of Y-BOCS in the group receiving Risperidone at the beginning and end of

study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170716035117N1**

Registration date: **2018-01-01, 1396/10/11**

Registration timing: **retrospective**

Last update: **2018-01-01, 1396/10/11**

Update count: **0**

Registration date

2018-01-01, 1396/10/11

Registrant information

Name

Reza Kookalani

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5541 0126

Email address

kookalani-r@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2017-07-11, 1396/04/20

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Aripiprazole and Risperidone in Improving Obsessive-compulsive symptoms in Bipolar patients Comorbid Obsessive-compulsive disorder

Public title

Effect of Aripiprazole and Risperidone in Improving Obsessive-compulsive symptoms in Bipolar patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age between 18 and 65 years A definitive diagnosis of Bipolar disorder with Obsessive-compulsive disorder based on DSM-5 criteria Bipolar patients in Maintenance phase Patients with ability to answer and evaluate with Yale Brown scale (Higher education level) Patients with Yale-Brown Obsessive-Compulsive Scale 16 or higher

Exclusion criteria:

Acute and severe physical illness during study Presence of unsafe pregnancy prevention method in women of reproductive age Pregnancy Bearst feeding Substance abuse and alcohol abuse in the six months before study Accompanied with other psychiatric disorders

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind (both patients and researchers) in your study are blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kshan University of Medical Sciencesa

Street address

Ghotbe Ravand Boulevard, Kashan University of Medical Sciences

City

Kashan

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Isfahan

Postal code

8715988141

Approval date

2017-05-16, 1396/02/26

Ethics committee reference number

IR.KAUMS.REC.1396.23

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

Obsessive-compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

2**Description of health condition studied**

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes**1****Description**

Severity obsessive compulsion

Timepoint

The beginning of the study and every four weeks until the twelfth week

Method of measurement

Yale Brown Obsessive-Compulsion Scale

Secondary outcomes

1

Description

The onset of side effects of drugs

Timepoint

Weeks four, eighth, twelfth

Method of measurement

Clinical examination

Intervention groups

1

Description

First intervention group: In addition to peptic stabilizers, aripiprazole is started at a dose of 2.5 mg and gradually administered to the end of the second week to 10 mg per day. The duration of use is 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention group2: In addition to mood stabilizers, Risperidone was started by 1 mg and gradually received 2 mg / day until the end of the first week. Duration of use is 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated to Kashan University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Qorishi

Street address

Kargar Nejad Hospital, Qotb Ravandi Blvd

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8715973446

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kargarnejad@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholam Ali Hamidi

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research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Fatemesadat Qoreishi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Assistant professor

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Reza Kookalani

Position

Assistant Of Psychiatry

Latest degree

Medical doctor