

# 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

**Province**

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

#### City

Esfahan

#### Province

Isfahan

#### Postal code

8715973446

#### Phone

+98 31 5554 9111

#### Email

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

#### Street address

Ghotbe Ravandi Blvd, Kashan

#### City

Kashan

#### Province

Isfahan

#### Postal code

8715988141

#### Phone

+98 31 5557 5057

#### Email

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

#### Street address

Kargar Nejad Hospital, Qotb Ravandi Blvd

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#### Province

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#### Postal code

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#### Fax

#### Email

dr.zoghoreishi@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Fateme Sadat Qoreishi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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rezakookalani@gmail.com

**Web page address**

## 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