Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
Isfehan
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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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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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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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