

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison Aripiprazole & Risperidone effectiveness in treating obsessive-compulsive disorder in patients with Bipolar disorder

Protocol summary

Study aim

Comparison Aripiprazole & Risperidone effectiveness in treating obsessive-compulsive in patients with bipolar disorder

Design

A randomized clinical trial without control group, with parallel groups, phase 3. without blindness that, 60 patients randomly divided into two groups of 30 subjects with block sizes of 4 and 6.

Settings and conduct

The population of this study was aged 18-55 years old who referred to Yahya Nezhad Hospital in Babol. Patients are randomly divided into two Intervention groups with a table of random numbers by computer. Intervention group 1: Aripiprazole (Sobhan Company) Begins with an initial dose of 2.5 mg per day and gradually increased to a dose of 5 to 20 mg per day. Intervention group 2: Risperidone (Porsina) Begins with an initial dose of 0.5 mg per day and gradually increased to a dose of 1 to 4 mg per day.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with bipolar mood disorder, Have not Major medical problem (cardiovascular, respiratory, renal and gastrointestinal disease) Exclusion Criteria: Pregnancy, alcohol or other substances abuser

Intervention groups

Intervention group 1: Aripiprazole (Sobhan Company) Begins with an initial dose of 2.5 mg per day and gradually increased to a dose of 5 to 20 mg per day. Intervention group 2: Risperidone (Porsina) Begins with an initial dose of 0.5 mg per day and gradually increased to a dose of 1 to 4 mg per day.

Main outcome variables

Efficacy of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200614047761N1**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

Registration date

2020-06-18, 1399/03/29

Registrant information

Name

sekineh javadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3229 1951

Email address

s.javadian@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-09, 1399/01/21

Expected recruitment end date

2021-04-10, 1400/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Aripiprazole & Risperidone effectiveness in treating obsessive-compulsive disorder in patients with Bipolar disorder

Public title

Treating obsessive-compulsive disorder in patients with Bipolar disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with bipolar mood disorder Have not Major medical problem (cardiovascular, respiratory, renal and gastrointestinal disease)

Exclusion criteria:

Pregnancy alcohol or other substances abuser

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients randomly divided into two groups of 30 subjects with four and six blocks and an allocation ratio of 1: 1. The participants allocation sequence in two groups performed with a Randomizer software. Opaque sealed sequentially numbered envelopes used for allocation concealment.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The Ethics Committee of Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2020-04-08, 1399/01/20

Ethics committee reference number

IR.MUBABOL.REC.1399.072

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

Bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

2**Description of health condition studied**

Obsessive-Compulsive disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

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

obsessive-compulsive signs&symptoms in bipolar disorder patients

Timepoint

before intervention and then monthly for 4 months

Method of measurement

Yale- Brown Obsessive Compulsive Scale questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Aripiprazole (Sobhan Company) Begins with an initial dose of 2.5 mg per day and gradually increased to a dose of 5 to 20 mg per day

Category

Treatment - Drugs

2**Description**

Intervention group: Risperidone (Porsina) Begins with an initial dose of 0.5 mg per day and gradually increased to a dose of 1 to 4 mg per day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahya Nezhad Hospital

Full name of responsible person

Sekineh Javadian

Street address

Shahid Mostafa Khomeini St., Modarres St

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Mazandaran

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4713566547

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Email

s.javadian@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Babol University Of Medical Sciences, Daneshgah Square, Ganjafrooz Avenue

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rezaghadimi@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Sekineh Javadian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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