

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparison of the effect of risperidone and aripiprazole as a clinical trial in treating the acute phase of mania in patients with bipolar disorders

#### Protocol summary

##### Study aim

Comparison of the effect of risperidone and aripiprazole as a clinical trial in treating the acute phase of mania in patients with bipolar disorders

##### Design

The clinical trial is comparative, with parallel groups, double-blind, randomized, phase 3 on 76 patients, the rand function of Excel software is used for randomization.

##### Settings and conduct

The patients under study are patients who referred to Farshchian Sina Psychiatric Hospital in Hamedan due to bipolar disorders. The confirmation that these patients have bipolar disorder is done by a psychiatric specialist. The study will be done in a double-blind manner, and the drugs will be delivered to the patients in the same form and appearance. Coding of the intervention groups is done by one of the experts of the psychiatric department of the hospital, and the research group will be unaware of the coding until the end of the research.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient consent to participate in the study Suffering from the acute phase of mania of bipolar disorder, which must be confirmed by a psychiatrist Non-entry criteria: History of hypersensitivity to risperidone and aripiprazole

##### Intervention groups

The number of patients is 76 who are divided into two groups of 38 and the amount of drug consumption in the two research groups is as follows. In the first group of resperidone, patients will be evaluated at intervals of one week and two weeks. In the second aripiprazole group, patients will be evaluated at intervals of one week and two weeks.

##### Main outcome variables

Compared to aripiprazole, the effectiveness of risperidone is different in the following cases: Increased energy, increased mood, increased libido, sleep disturbance, excitability, talkativeness, thought disorder,

thought content disorder, aggression, appearance grooming; Insight into the disease

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231022059813N1**

Registration date: **2023-12-14, 1402/09/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-14, 1402/09/23**

Update count: **0**

##### Registration date

2023-12-14, 1402/09/23

##### Registrant information

##### Name

seyed mostafa mousavi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3320 5264

##### Email address

m.mousavi@edu.umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-11-21, 1403/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of risperidone and aripiprazole as a clinical trial in treating the acute phase of mania in patients with bipolar disorders

**Public title**

Comparison of the effect of risperidone and aripiprazole in the treatment of the acute phase of mania

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patient consent to participate in the study Suffering from the acute phase of mania of bipolar disorder, which must be confirmed by a psychiatrist

**Exclusion criteria:**

History of sensitivity and allergy to aripiprazole and risperidone Physical illness

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **76**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, volunteers will be assigned to two groups by simple randomization method. The drugs used are delivered to the patients in a similar form and appearance. Coding of the intervention groups is done by one of the experts of the psychiatric department of the hospital, and the research group will be unaware of the coding until the end of the research. In order to randomize people into two groups, calculator.net online software generated 76 random numbers between the numbers 1 and 76, and the numbers generated in the range {1-38} were assigned to the control group and the numbers generated in the range {39-76} were assigned to the intervention group, which is shown in the following sequence:

BBBABBBBBBAAAABBAABBAABBBAAAABABAAABBBABAA  
ABBBBBBBAAAABBABABAAABBBBABAAAAAAA

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The used drugs are delivered to the mentioned patients in a similar form and appearance. Coding of the intervention groups will be done by one of the experts of the psychiatric department of the hospital, and the research group (participant and clinical caregiver and

researcher and outcome evaluator) will be unaware of the coding until the end of the research.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

**Street address**

Nasser Khosrokh Street, Shahid Timuri Street, Yadgar Imam Som Alley

**City**

Khorramabad

**Province**

Lorestan

**Postal code**

6816947174

**Approval date**

2023-07-18, 1402/04/27

**Ethics committee reference number**

1402.427.IR.UMSHA.REC

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

Comparison of the effect of risperidone and aripiprazole as a clinical trial in treating the acute phase of mania in patients with bipolar disorders

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Comparison of risperidone and aripiprazole in the treatment of manic phase of bipolar disorder

**Timepoint**

The beginning of the study and 7 and 14 days after the beginning of the mania phase

**Method of measurement**

Jung's Mania Rating Questionnaire

**Secondary outcomes**

## 1

### **Description**

Comparison of risperidone and aripiprazole in increasing energy

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 2

### **Description**

Comparison of risperidone and aripiprazole in elevated mood

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 3

### **Description**

Comparison of risperidone and aripiprazole in increasing libido

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 4

### **Description**

Comparison of risperidone and aripiprazole in sleep disorder

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 5

### **Description**

Comparison of risperidone and aripiprazole in irritability

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 6

### **Description**

Comparison of risperidone and aripiprazole in talkative speech

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 7

### **Description**

Comparison of risperidone and aripiprazole in thought disorder

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 8

### **Description**

Comparison of risperidone and aripiprazole in Thought content disorder

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 9

### **Description**

Comparison of risperidone and aripiprazole in aggression

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 10

### **Description**

Comparison of risperidone and aripiprazole in appearance beauty

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## 11

### **Description**

Comparison of risperidone and aripiprazole in disease insight

### **Timepoint**

At the beginning of the study and 7, 14 days after starting to take the drug

### **Method of measurement**

Yang's Mania Rating Questionnaire

## **Intervention groups**

## 1

### **Description**

Intervention group 1: Risperidone 2 mg tablet of Biopharma company once a night and sodium valproate tablet of Raha company 500 mg a night orally for two weeks

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: Aripiprazole 10 mg tablet of Sobhan Shabi company and sodium valproate tablet of Raha company 500 mg once orally during two weeks

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina Hamedan Hospital

**Full name of responsible person**

Seyed Mustafa Mousavi

**Street address**

Mirzadeh Eshghi St

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6516848741

**Phone**

+98 81 3827 4191

**Email**

hosp\_sina@sina.tums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokohi

**Street address**

Hamedan, Shahid Fahmida Blvd

**City**

Hamedan

**Province**

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**Phone**

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it.amoozesh@umsha.ac.ir

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Seyed Mustafa Mousavi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Seyed Mustafa Mousavi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Seyyed Mustafa Mousavi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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**Phone****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