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:
BBBABBBBBBAAAABBAABBAABBBAAAABABAAABBBABAAABBBBBBBAAAAABBABABAAABBBBABAAAAAAA

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: Resperidone 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
Hamadan
Postal code
۶۵۱۷۸۳۸۷۳۶
Phone
+98 81 3131 0000
Email
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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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